Background of the Tuberculosis Emergency Declaration

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**Abstract:** Following the long-lasting smooth decline after the war, the improvement of tuberculosis situation in Japan has been slowed since the 1980's and the trend has become reversed after 1996.Basically it is related to the rapid ageing of the population with the growing of the heavily infected population segment born during early decades of the last century. As a result, Japan’s tuberculosis case rate remains at a quite high level, i.e., about 6 times that of USA, or the level of USA’s late 1950. At the same time, there is a remarkable concentration of TB patients on more susceptible populations such as medically compromised people or socio-economically deprived people. This has changed the clinical and managerial aspects of TB greatly, requiring more intensive care for each patient including care for underlying illnesses, drug side-effects, and social and psychological support for completing treatment, such as DOTS. Enhancing social and professional concern to this problem is urgently needed in order to respond to the Declaration of TB Emergency most properly.

**Key words:** Tuberculosis control; Risk factor; Socio-economic factor; Patient management; DOTS

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**Why TB Emergency Now?**

The decrease in the TB case rate in Japan had been slower since around 1980, and finally in 1996 the case rate began to go upwards. From 1997 through 1999, there has been an increase in the rate for three consecutive years for the first time after World War II. (Fig. 1)

This could be seen as a temporary tumult in a long lasting and steady downward tide of tuberculosis epidemiology, although there is a substantial influence of rapid ageing of the population after the war. However, depending on how we deal with that in the coming few years, this trend might give a birth to a new problem. We have a lot to learn from the example of the United States, where TB had been on the increase from the late 80’s to the early 90’s due to the neglect in TB control services. In fact, it can be said that the same signs
have began to appear partly in Japan. Moreover, it seems that the response from various quarters to the problem has been somewhat unconcerned in effect. The tuberculosis emergency announced by the Minister of Health and Welfare in July 1999 has been regarded as drawing serious attentions to such a situation. Following this announcement, this paper examines the current situation of TB control and discusses how it should be in the future.

Increase in Cases with More Serious and Difficult Disease

The proportion of bacteriologically confirmed cases among newly registered cases, which is used to measure the seriousness of the condition of new TB patients, shows a significant increase from 19% in 1975 to 55% in 1999. Although, of course, it has to be taken into account that bacteriological examinations had become widespread and bacteriological findings had come to be considered more important during this period, this still seems to indicate that more patients have serious disease at the time of onset, and/or that tuberculosis is more likely to be detected only after it becomes very serious.

As a result, the prognosis of patients in terms of their fatality has also worsened. The case fatality rate of the patients, which is estimated by dividing the number of patients who died within 1 year after they were registered by the number newly registered cases, has increased from 1.8% in 1989 to 2.9% in 1999. According to some source, 12% of the smear positive patients who have never been treated for tuberculosis before have died within 9 months after the treatment began.

Another issue to be warned for beside the above tendency is that the drug resistance is also on the increase. According to a nationwide survey on drug resistant tuberculosis conducted in 1997, 10.2% of patients who had never received TB treatment before had resistance to one or more major drugs at the start of their treatment, and among them 4.2% had resistance to isoniazid (INH), which has a particularly important role in tuberculosis treatment. Also, regarding those who had previously received treatment, more than 40% had some resistance and in particular, over 20% were resistant to both INH and rifampiscin (RFP), i.e., the nucleus of drug regimen in the current treatment (multi-drug resistance).

This may seem relatively better in comparison with the US data showing the initial drug resistance between 1992 and 1996; 13% to some drugs, 8% to INH and 2% to both INH and RFP. Nevertheless, it is necessary to carefully consider this matter, since the number of patients with difficulties in receiving treatment will increase for medical and social reasons as discussed below.

The current problems in TB incidence and its treatment are summarized in the points that I raise as following. First, the development of TB is concentrated on medically compromised subjects including the aged and others, and thus their conditions tend to get severe. In 1999, 58% of newly recorded patients were over 60 years old, and 40% were over 70 years old. In addition, the population over 80 and 90 years old has been experiencing a remarkable increase in the case rate.
According to a survey conducted in Yamagata Prefecture, 14% of newly registered patients had diabetes. Similarly, 14% had a history of gastrectomy or under treatment for stomach ulcer, 6% under treatment for malignancies, 4% under treatment with corticosteroids, 3% with renal failure (under hemodialysis), etc. It is not difficult to imagine that once individuals with such medical risks present TB symptoms, they would easily develop them into severe conditions.

Drifting of TB to Socioeconomically Fragile Population

Another factor for the increase of TB patients that readily get into severe conditions is that the TB occurrence is concentrated on socioeconomically fragile people. The case rate of Nishinari Public Health Center, Osaka City that has “Airin Area” within its jurisdiction is 535 per 100,000 population, i.e., 14 times as high as the national average. The case rate estimated specifically for the homeless and the slum inhabitants is as much as 1,500–2,000. The concentration of TB incidence has also been observed in poor families and those engaged in service businesses or working in small companies. As shown in Fig. 2 the number of the newly registered cases with positive bacteriology in service businesses has also been clearly increasing. It would be fare to say that one of the factors for this is inadequate health care in everyday life. However, it has been known that regarding newly recorded patients there is a strong correlation between the proportion of patients detected by health examinations and the proportion of those with smear positive cases among all new cases according to the type of occupation: in occupations such as nurses and teachers, the proportion of patients detected in health examinations is high and the proportion of smear positive cases is low; on the contrary, for the unemployed and the self-employed that have less chances to have health examinations, the proportion of patients detected in health examinations is low and proportion of smear positive cases is high. Thus, we should take it into consideration that administrative failure in extending such services to the socioeconomically weaker people may have contributed to the increase of TB among these occupations.

Fig. 2 Changes in the number of newly registered patients in different occupations
Improving Hospital Treatment

Next, I would like to summarize how tuberculosis medical services have been affected by the ever-continuing qualitative changes of patients in the midst of the TB upsurge.

First, it is becoming more important to detect TB patients in general consultations. It is commonly observed that the aged who have medical consultations for various medical problems are often found to have TB, or those who have less chances to have health examinations belatedly visit medical facilities due to the symptoms and are diagnosed as TB. As a result of this, 80% of patients in all age groups, and 90% in the age of 60 or over, have been detected in consultations at medical facilities due to the symptoms. Thus, patient detection in earlier stages of clinical setting rather than in health examination is becoming increasingly important. The result of inadequate functioning of this process has been the increase of patients with serious conditions and poorer prognosis as well as problems such as outbreak of small epidemics and nosocomial infections of tuberculosis. It is particularly necessary to implant and maintain the awareness of ‘TB is still around!’ both under- and post-graduate training of physicians.

Next, TB treatment is becoming more necessary in general consultations. As discussed above, TB patients with medical complications or underlying conditions are on the increase. Also, treatment for side effects of anti-tuberculosis medications is difficult. For TB treatment, these patients are often moved to TB beds, i.e., TB ward under the current legislation of medical facilities; nevertheless, that leads to the problem that treatment for underlying illnesses tends to be neglected. It is hoped that in the future a certain number of TB beds will be placed in general wards and both underlying illnesses and TB will be treated there. The Ministry of Health and Welfare has already been promoting the provision of such hospital room under the subsidiary program named “Model TB Beds Program” since 1992. Although this program is aimed at providing subsidies for reforming a general hospital bedroom for the infection control so that TB patients can be accommodated safely, it seems that that has not been working quite well in practice.

Issues of Patient Support

Also, the importance of patient education is being reconsidered. The increase of socio-economically deprived patients indicates that completion of the treatment on a regular base will be difficult. The problems are caused by their maladaptation to hospital treatment and economic problems, etc. The best strategy for this is DOT, directly observed therapy. This is a strong patient management system where patients with difficulties in continuing hospital treatment and are discharged come to the hospital everyday and take drugs under the observation of the staff like nurses, combined with human communication between the patients and the staff, support as required, and visits the patients’ houses when they do not attend the hospital. This program has been successful in New York as well as in developing nations. Also in Japan, although on a small scale, the program has been implemented in San-ya Area of Tokyo, Kotobuki Area of Yokohama City, Airin Area of Osaka City, and been successful. However, since hospital treatment is more readily available in Japan, it is hoped to establish a more flexible system where hospitals have a well working appointment system for OPD to check patients’ regular attendance and a public health center in cooperation conducts education and support patients that are defaulting from regular drug taking and hospital attendance, rather than rigorous patient management like DOT that may not be practicable everywhere. We should also consider that there would be a time in the future when treatment under detention that has been conducted in many states of the USA will be considered for more uncooperative patients.
Urgent Problems in Provision of TB Treatment Service

Apart from these general matters, however, there are several problems that have to be urgently dealt with. First, it is feared that TB patients might not be able to be hospitalized. Currently there are about 13,000 of TB beds that are specifically designated to accommodate infectious TB patients, and actually 60% of them have been occupied. However, their distribution is uneven, varying from place to place. It has been increasingly observed in some areas, especially in large cities that over 90% of them have been occupied. However, their distribution is uneven, varying from place to place. It has been increasingly observed in some areas, especially in large cities that over 90% of them have been occupied. In those areas, patients currently discharging TB bacilli are unable to be hospitalized and thus have to wait, or be hospitalized in inconvenient, distant facilities. It is worried that the motivation for managing the hospital may be lowered due to the unprofitability and laboriousness of TB treatment, and the situation has been worsened by the abolition and conversion national and other public hospitals.

The next problem is that anti-TB drugs may be unavailable. Capreomycin became uncovered by the health insurance and the TB control law in 1997. It has been alleged that this is because of the unprofitability resulting from the too low drug cost. Some other drugs such as ethionamide, cycloserine, and PAS have in the past faced the supply crisis for similar reasons. As we cannot have the pharmaceutical industry continue to sell products at their cost, it is needed to consider the revision of price list of drugs to a reasonable level.

Also, the authorization of new drugs that are to be used for TB treatment has been delayed. In many foreign countries, drugs such as quinolones are widely prescribed for patients with drug-resistance. However, in Japan these have not been approved by insurance nor TB Control law due to the difficulties in conducting clinical trials that are required for the formal approval procedure. In many other nations, the use of these drugs has been permitted due to the urgent demands. Adaptable administrative actions are urgently needed for exceptional approvals of these drugs.

Thus, it has to be said that the situation surrounding TB treatment in Japan is rather inactive. The medical expenditure for TB amounts merely 0.4% of the whole medical expenses in 1998. It was 27% in 1955. The wise utilization of this small amount of money would protect patients and surrounding people, and in turn
bring about the security to the national population for the decade to come. In order to achieve this, the awareness “TB is still around!” has to be raised still higher.

Comments

The case rate of TB in Japan is 38 per 100,000 population, which is 6 times as high as the US figure. USA passed this standard already in the 1950’s (Fig. 3). As this is currently on the increase, the entire medical community of Japan should reconsider TB with new perspectives and take necessary actions. I believe that that is the responsibility for medicine as a response to the TB Emergency Declaration.

REFERENCES