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Studies on Risk of Leprosy Relapses in China: Relapses After Treatment with Multidrug Therapy[1]

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Multidrug therapy as advised by the World Health Organization (WHO/MDT) ([21]) was introduced nationwide in 1986 in China on the basis of the experience obtained from field trials in the pilot areas in 1983. At the beginning of the MDT introduction in the country, the leprosy control program with fixed-duration WHO/MDT was implemented in the most prevalent and the most difficult areas; whereas the program with WHO/MDT until skin-smear negativity in multibacillary (MB) patients was adopted in the economically developed coastal areas according to the standards set at the National Leprosy Technical Conference in Nanjing in 1982 ([11]). Up to 1997, nearly 55,000 leprosy patients had been treated with WHO/MDT, of whom more than 48,000 had completed their treatment. In order to assess the efficiency of the presently used WHO/MDT and throw some light on the surveillance of patients released from the regimens, it is necessary to have some insight into the relapses in these patients. This paper reports on the relapses detected among the patients cured by or released from WHO/MDT and followed up for 1–13 years.

MATERIALS AND METHODS

The National System for Leprosy Surveillance was initiated by the Chinese Ministry of Public Health in 1989, and is responsible for the epidemiological analysis of the leprosy situation in order to provide timely information to the governmental authorities for their policy making. Up until the end of 1998, a national database for all leprosy patients detected since the founding of the People's Republic of China until the year 1997 had been established. This database covers all leprosy patients from the 27 provinces, municipalities or autonomous regions (PMRs) in the country, excluding three nonendemic areas (Beijing, Inner Mongolia and Shanxi) as well as Taiwan Province and Hong Kong Special Administrative Region. The present study was made on the basis of this national database.

Patients and follow up. The subjects entered into this study were patients who had received treatment with WHO/MDT, including the patients treated with WHO/MDT alone or previous dapsone (DDS) monotherapy and then WHO/MDT, and had been declared clinically cured or released from treatment and followed up for more than half a year. After release from WHO/ MDT, an active annual follow up is required for at least 5 and 10 years in WHO/MDT-paucibacillary (PB) and WHO/MDT-multibacillary (MB) patients, according to the leprosy control program in China. Subsequently, the irregular active and/or passive follow up is carried out according to the local program. For patients who had been released from active follow up, the deadline for these patients to be excluded from the cohort of follow up was determined on the basis of the life expectancy of the population. For treatment regimens, 6 monthly doses of WHO/MDT were prescribed for PB patients and for MB patients two regimens were given, one of which was 24 monthly doses of treatment which was defined as fixed-duration treatment (FD-MB) and another was treatment until skin-smear negativity (SN-MB). A total of

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47,276 leprosy cases met the criteria of follow up for the present study. Between 1949 and 1997, 12,524 patients relapsed, of whom 221 relapsed after WHO/MDT treatment, accounting for 1.76% of the total relapses. The relevant data for all subjects were collected with the specialized forms in the county station for skin diseases control through the local leprosy program. All forms were sent to the National Center for STD and Leprosy Control after being checked by the leprosy authorities at the provincial level. Data were entered into a computer to establish the databank for further analysis.

Criteria of relapses. Criteria of relapse after WHO/MDT were defined as an insidious appearance of new lesions and/or enlargement of old lesions after completing a prescribed course of treatment or declaring clinical cure. In addition to these, the criteria in MB patients still included an increase in acid-fast bacilli (AFB) by at least 2+ from the same site as a previous skin smear and the specific infiltration plus positive AFB in the histopathology of a suspected lesion. If any patient was suspected to relapse after WHO/MDT, further examinations should be made by the provincial or national experts in order to confirm the diagnosis. The examinations included repeated physical examination, re-testing skin smears, a biopsy for histopathological examination, and conducting mouse foot pad inoculation wherever possible.

Statistical analysis. The number of patients who relapsed during follow up was used as the numerator and the number of patients who reached clinical cure or were released from WHO/MDT treatment and their total follow-up duration in terms of patient-years (PY) was used as the denominator for the calculation of relapse rates per 100 patients or per 1000 PY. The duration in years of follow up was defined as the period from the calendar year of clinical cure or release from treatment to the year of the patient's exclusion from the cohort of follow up or the end of 1997. The incubation period was calculated as the period between clinical cure or release from WHO/MDT and the diagnosis of relapse. For statistical significance, the chi-squared (χ^2) test and χ^2 test for trend were applied for comparison of percentages or relapse rates and their trends, respectively, the Student's *t* test for comparison of mean periods of follow up or mean incubation of relapses, and the linear regression analysis (calculation of correlation coefficient and its ANOVA, i.e., F statistic) for determination of the correlation between two variables (calendar years and the proportions) by means of the STATA v.3.0 or Epi-Info 5.0 program. The p values of less than 0.05 are considered to be statistically significant.

RESULTS

Between 1983 and 1997, a total of 54,651 patients had been treated with WHO/MDT regimens. Among the 47,276 patients in the present study, 48.5% were treated with WHO/MDT regimens alone and 51.5% were treated with previous DDS plus WHO/MDT. Figure 1 shows the number of relapsed cases after WHO/MDT as the proportion among the total of patients detected and relapsed at 2-year intervals between 1986 and 1997. It was found that the WHO/MDT relapsed cases accounted for a small percentage of the totally detected cases or relapsed cases, but this proportion had a significant tendency to increase with calendar years ($r = 0.85$, $F = 10.74$, $p < 0.05$), particularly the proportion of WHO/MDT-relapsed cases among the totally relapsed cases significantly increased from 0.67% in 1986–1987 to 11.79% and 7.92% in 1994–1995 and 1996–1997, respectively ($r = 0.93$, $F = 25.02$, $p < 0.01$).

For the 47,276 patients cured by or released from MDT treatment, 221 patients (90 PB, 82 FD-MB and 49 SN-MB) relapsed with an overall relapse rate of 0.73 per 1000 PY over an average follow-up period of 6.36 ± 2.83 years. This rate was significantly lower than that in DDS-cured cases in the same areas ($\chi^2 = 399.3$, $p < 0.001$). The relapse rate in patients treated with WHO/MDT-PB (1.04 per 1000 PY) was significantly higher than in patients treated with WHO/MDT-MB (0.61 per 1000 PY) ($\chi^2 = 15.7$, $p < 0.01$). The overall relapse rate (1.44 per 1000 PY) in WHO/MDT-PB patients with previous DDS monotherapy was significantly higher than those without previous DDS (0.68 per 1000 PY, $\chi^2 = 11.8$, $p < 0.01$). But the difference between WHO/MDT-MB patients with (0.65 per 1000 PY) and without (0.54 per 1000 PY)

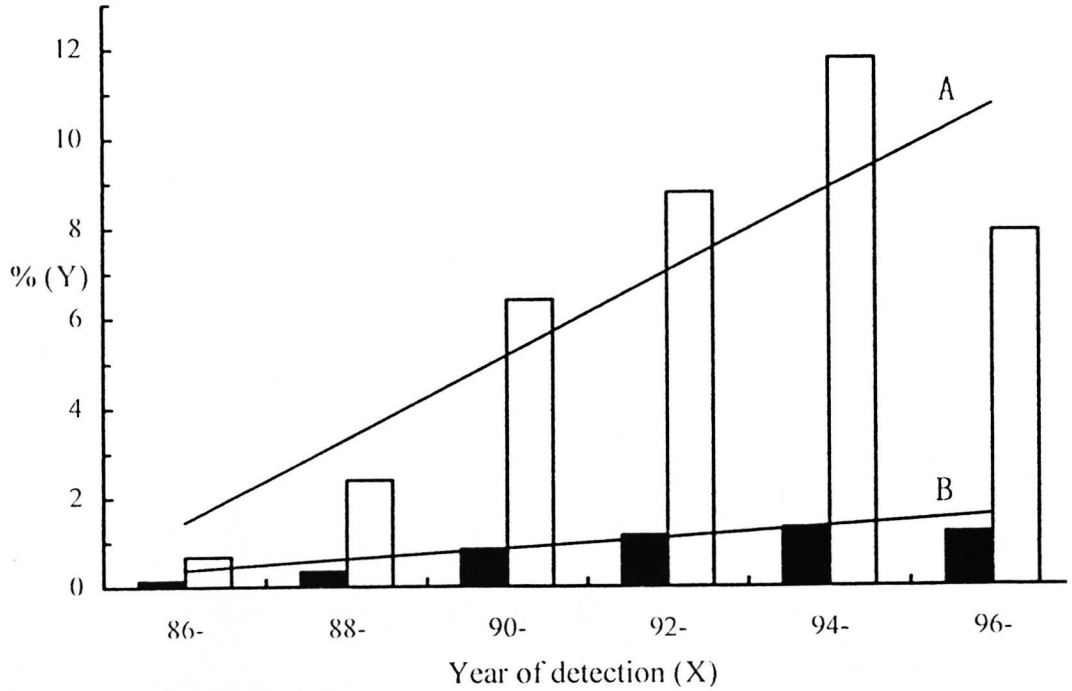

FIG. 1. Cases relapsed after WHO/MDT as a proportion of all detected or all relapsed cases, 1989–1997. □ = Proportion among all relapsed cases—A: Y = –79.00 + 0.93X, r = 0.854, p <0.05. ■ = Proportion among all detected cases—B: Y = –10.02 + 0.12X, r = 0.929, p <0.01.

previous DDS monotherapy was not significant (χ^2 = 0.86, p >0.05). The relapse rate in FD-MB cases also was not significantly different from SN-MB (χ^2 = 2.2, p >0.05). The incubation period between clinical cure and relapse was similar in WHO/MDT-MB (3.71 ± 2.56 years) and WHO/MDT-PB (3.76 ± 2.39 years) treated cases (t = 0.15, p >0.05), but the average period of follow up in WHO/MDT-PB cases (7.11 ± 3.01 years) was significantly longer than in WHO/ MDT-MB cases (6.11 ± 2.71 years) (t = 34.04, p <0.01). For the patients cured with WHO/MDT-MB, there was no significant difference between the patients with FD-MB and SN-MB treatment in terms of the average incubation period (t = 0.37, p >0.05) and the mean period of follow up (t = 1.60, p >0.05) (Table 1).

The percentages of relapses by WHO/MDT regimens in 2-year incubation intervals for patients treated with WHO/ MDT are presented in Figure 2. There was a higher percentage of WHO/MDT-PB patients (37.8%) whose relapses occurred during the first 2 years compared with WHO/ MDT-MB patients (37.4%). Of relapses with WHO/MDT-MB, 47.8% of patients relapsed during 3–6 years of follow up and about 15% occurred after 6 years of follow up.

Table 2 presents the risk of relapse at 2-year intervals of follow up after WHO/ MDT. The rates of relapse varied significantly from year to year in both WHO/ MDT-MB and WHO/MDT-PB patients (χ^2 = 326.0 and 376.8, respectively, both p <0.01); the rates decreased significantly after 6 years of follow up. In the 13th year after stopping treatment, the relapse rate (0.68/1000 PY) showed a nonsignificant increase compared to the 11th to 12th years (0.17/1000 PY) (χ^2 = 1.74, p >0.05) when the WHO/MDT-MB and WHO/MDT-PB patients were taken together, but the increase was statistically significant in WHO/ MDT-MB patients. The risk of relapse was consistently higher in WHO/MDT-PB patients than in WHO/MDT-MB patients over the first 8 years (p <0.01). After 8 years of follow up, the rate was higher in WHO/ MDT-MB than in WHO/MDT-PB cases, but the difference was not statistically significant.

TABLE 1. *Risk of relapses in 43,270 cases released from MDT (1984–1987).*

MDT regimens[a]	No. cases observed	Average yrs. of follow up	No. cases relapsed	Average yrs. incubation	Relapse per 100 cases	Relapse rate[b]	χ^2 Value
MDT-PB	12,136	7.11 ± 3.01	90	3.76 ± 2.39	0.74	1.04	15.7[c]
PDDS(+)	4,926	8.31 ± 2.69	59	3.92 ± 2.42	1.20	1.44	11.8[d]
PDDS(–)	7,210	6.28 ± 2.93	31	3.45 ± 2.31	0.43	0.68	
MDT-MB	35,140	6.11 ± 2.71	131	3.71 ± 2.56	0.37	0.61	
FD-MB	24,164	6.09 ± 2.58	82	3.64 ± 2.60	0.34	0.56	2.20[e]
SN-MB	10,976	6.14 ± 2.98	49	3.81 ± 2.49	0.45	0.73	
PDDS(+)	19,399	7.08 ± 2.46	89	3.90 ± 2.47	0.46	0.65	0.86[f]
PDDS(–)	15,741	4.90 ± 2.52	42	3.31 ± 2.69	0.27	0.54	
Total	47,276	6.36 ± 2.83	221	3.74 ± 2.53	0.47	0.73	

[a] MDT-MB = MDT for MB cases; PDDS(+) = MDT with previous DDS; FD-MB = fixed duration of MDT for MB; MDT-PB = MDT for PB cases; PDDS(–) = MDT without previous DDS; SN-MB = MDT for MB until skin-smear negativity.

[b] Rate per 1000 PY.

[c] Comparison between MDT-PB and MDT-MB, $p < 0.01$.

[d] Comparison between PDDS(+) and PDDS(–) in patients with MDT-PB, $p < 0.01$.

[e] Comparison between FD-MB and SN-MB, $p > 0.05$.

[f] Comparison between PDDS(+) and PDDS(–) in patients with MDT-MB, $p > 0.05$.

The leprosy classification as originally identified at the first presentation of the disease and at the time of relapse is summarized in Table 3. All 126 patients originally classified as MB leprosy relapsed with MB leprosy; whereas among 95 patients with an original classification of PB leprosy, more than half (55.8%) relapsed with MB leprosy, indicating more patients whose leprosy types changed from PB to MB ($\chi^2 = 68.5$, $p < 0.01$).

DISCUSSION

Relapse in leprosy is not only one of the important problems in a leprosy control program, it also can provide the ultimate proof of successful treatment of the disease, even though regimens also need to be as-

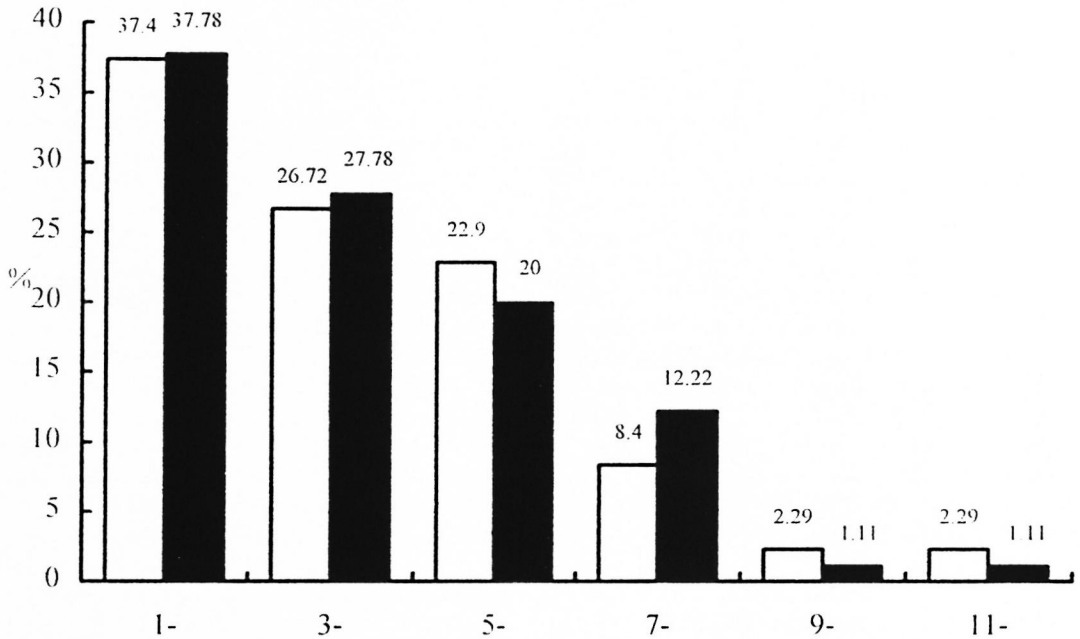

FIG. 2. Relapse in period as a proportion of all relapses after release from MDT treatment, 1984–1997. □ = WHO/MDT-MB; ■ = WHO/MDT-PB.

TABLE 2. *Risk of relapses in 2-year follow-up periods of 47,276 cases released from multidrug therapy (MDT)[a], 1984–1997.*

Follow-up periods in years	No. cases relapsed			Relapse rate per 100 cases			Rate per 1000 PY			
	MDT-MB	MDT-PB	Total	MDT-MB	MDT-PB	Total	MDT-MB	MDT-PB	Total	χ^2 Value[b]
1–2	49	34	83	0.90	2.24	1.19	5.98	16.24	8.07	21.9*
3–4	35	25	60	0.80	2.38	1.11	2.28	6.82	3.16	19.4*
5–6	30	18	48	0.50	1.23	0.64	0.90	2.21	1.15	9.8*
7–8	11	11	22	0.09	0.36	0.14	0.12	0.48	0.19	12.7*
9–10	3	1	4s	0.05	0.02	0.04	0.05	0.03	0.04	0.5
11–12	2	1	3	0.26	0.12	0.19	0.23	0.11	0.17	0.4
13	1	0	1	3.57	0.00	0.88	2.75	0.00	0.68	3.0
Total	131	90	221	0.37	0.74	0.47	0.61	1.04	0.73	15.7*
χ^2 value[c]	—	—	—	90.5*	114.8*	181.5*	326.0*	376.8*	624.9*	—

[a] Including previous DDS then MDT.
[b] Comparison of relapse rates per 1000 PY between MDT-MB and MDT-PB, * = $p < 0.01$.
[c] Chi-squared test for trend of relapse rates per 1000 PY among follow-up periods, * = $p < 0.01$.

sessed in terms of other aspects, including acceptability, toxic side effects, treatment duration, and cost. The present study analyzed the risk of relapses in patients treated with WHO/MDT for the purpose of enhancing our correct understanding of this problem. As mentioned in our previous report ([3]), this study came from a national project composed of all the patients treated with WHO/MDT in a large country, and it can, in some sense, really demonstrate the relapse problem of WHO/MDT.

WHO-recommended MDT was primarily used as a clinical trial in limited areas in China in 1983. Two years later, a few relapses began to be reported. At that time, because only a few patients had received the regimens and fewer patients had completed the treatment course and been followed up for only a limited period, these relapsed cases accounted for only a small part of the total in either the newly detected cases (0.14%) or the relapsed cases (0.67%). However, as more patients received treatment with WHO/MDT and then completed the regimens to enter the cohort for follow up and follow up was for a longer period, the proportions of WHO/MDT-treated patients significantly increased year by year ($r \geq 0.85$, $p < 0.05$), particularly the proportion of all relapsed cases, reaching 11.79% during the years 1994–1995. This trend is contrary to the relapse situation in DDS monotherapy in which the proportions have gradually come down year by year ([3]).

In the present study, more than half the patients relapsed from PB to MB; whereas no patient relapsed from MB to PB (Table 3), which was consistent with the findings of Dasananjali ([4]) and Li, *et al.* ([10]) in addition to the natural reversion of leprosy types, this phenomenon could be partly attributed to (in addition to the possibility of wrong initial classification) the fact that leprosy workers in the field predominantly

TABLE 3. *Original versus relapse classification in 221 cases relapsed after released from MDT treatment.*

Original classification by regimen[a]	Relapse classification[a]					
	MB		PB		Total	
	No. cases	%	No. cases	%	No. cases	%
MB	126	100.0	0	0.0	126	100.0
PB	53	55.8	42	44.2	95	100.0
		$\chi^2 = 68.5$, $p < 0.01$				
Total	179	81.0	42	19.0	221	100.0

[a] Classification was based on clinical classification.

TABLE 4. *Relapse rates in MB patients after treatment with MDT in the different large-scale studies (>1000 patients being followed up).*

Study (ref. no.)	Country	No. patients	Follow-up years	Relapse rate[a]
Becx-Bleumink ([2])	Ethiopia	2,379	4.7	2.4
WHO ([20])	Multi-center	20,141	9	0.84
Dasananjali ([4])	Thailand	2,624	<10	0.41
WHO ([19])	India	1,748	≤10	0.26
Li, *et al.* ([10])	China	5,981	4.5	0.15
Present study	China	35,140	6.1	0.61

[a] Rates per 1000 patient-years.

allocated relapsed patients into the MB group for purposes of treatment ([14]). Also, there have been changes of MB definition ([20]), resulting in more patients whose classifications changed from PB to MB after relapse. This might be partly supported by the fact that in the present study the proportion of relapsed cases diagnosed as MB leprosy was higher after 1993 (71/86, 82.6%) than before 1994 (94/135, 69.6%, $\chi^2 = 4.64$, $p < 0.05$).

Since the introduction of WHO/MDT in 1982, several studies have been carried out on relapses following release from treatment. During recent years, some well-documented studies have been published. It was quoted that the relapse rate is well below 1% with WHO/MDT ([1]). However, the rates have been variably reported by authors from different parts of the country and the world, ranging from as low as 0% in MB patients reported by Becx-Bleumink ([2]) or even in MB patients with high bacterial indexes followed for a minimum of 4 years ([9]) to as high as 17.7% in the study by the Marchoux Chemotherapy Study Group ([12]), and rarely 20% reported by Jamet, *et al.* ([8]). It is well known that the possible explanation for this wide variation is very likely due to the difference in the criteria employed for diagnosis of relapse and classification of the disease in different studies. Based upon the results from various studies, Ponnighaus and Sterne ([15]) indicated that unlike relapse after dapsone monotherapy, the cumulative probability of relapse is near to zero in MB patients and up to 5% in PB patients 10 years after completion of WHO/MDT if strict definitions of relapse are used. As in many studies ([13, 15, 19]), the risk of relapse in WHO/MDT-PB patients (0.74% or 1.04 per 1000 PY) in the present study was significantly higher than that in WHO/MDT-MB patients (0.37% or 0.61 per 1000 PY). However, it was found that the relapse rates in WHO/MDT-MB patients after 8 years of follow up were slightly higher than those in MDT-PB patients, but the differences were not statistically significant.

In addition to the operation factors which may affect the relapse rates, the number of patients for observation of relapse, as another important factor, has significantly varied between studies. Tables 4 and 5 show the relapse rates after WHO/MDT from part of the studies in which more than 1000 patients were followed up.

For MB patients, the overall relapse rate of 0.83 per 1000 PY over an average observation period of 4.7 ± 2.4 years in the pres-

TABLE 5. *Relapse rates in PB patients after treatment with MDT in the different large-scale studies (>1000 patients being followed up).*

Study (ref. no.)	Country	No. patients	Years of follow up	Relapse rate[a]
Grugni, *et al.* ([7])	India	1,509	≤5	17.5
Ekambaram and Rao ([6])	India	14,277	1	3.4
Becx-Bleumink ([2])	Ethiopia	3,065	6.1	2.4
WHO ([19])	Multi-center	51,553	9	1.70
Dasananjali ([4])	Thailand	5,298	<10	1.55
Li, *et al.* ([10])	China	2,326	5	0.55
Present study	China	12,136	7.1	1.04

[a] Rates per 1000 patient-years.

ent study was higher than those observed from the studies in selected areas in Thailand ([4]), India ([19]) and the three southwestern provinces of China ([10]), but lower than 0.84 per 1000 PY found by the WHO extended questionnaire survey in 28 selected programs ([19]) and much lower than that reported by Becx-Bleumink ([2]) in Ethiopia with a similar duration of follow up (Table 4). The difference in relapse rates between documented reports and our studies may be mainly related to the different geographic coverage and numbers of patients observed in different studies.

For PB patients, the highest relapse rate was reported by Grugni, *et al.* ([7]) in a study in which 85 of 1509 patients relapsed during a follow-up period of less than 5 years, giving a relapse rate of 17.5/1000 PY. The findings in the present study of relapse rate of 1.04 per 1000 PY during an average period of 7.11 ± 3.01 years after release from WHO/MDT were significantly lower than the rates depicted in Table 4, except that observed by Li, *et al.* ([10]) in selected areas in China.

The duration of follow up required in leprosy after completing WHO/MDT to give an adequate overall assessment of subsequent relapse rates is not yet known ([18]). However, some studies have shown that relapses occur late, usually more than 5 years after release from WHO/MDT treatment ([5, 12, 16, 17]). Therefore, Waters ([18]) suggested that the follow up needs to be longer than 5 years, probably 8–10 years, in order to give a good assessment of relapse rates. In the present study, a total of 47,276 WHO/MDT-treated patients were observed between 1984 and 1997, an average period of follow up of 6.36 ± 2.83 years. About 33.4% of the patients were followed up for a period of not more than 5 years, which may imply that the findings in the present study may not completely reflect the overall situation of relapse risk after MDT in China because of the relatively short period of follow up. The relapse rate may be high if the follow-up period extends longer, but it could be expected that the rate is not as high as that observed in some studies ([8]).

The risk of relapse in patients with DDS monotherapy before WHO/MDT was higher than for those without DDS monotherapy in both PB and MB patients. The difference was only statistically significant in WHO/MDT-PB patients, but it was not significant in MDT-MB patients as seen in some areas ([10]). The reason for the difference in PB patients remains to be further investigated.

With the introduction of MDT, as recommended by WHO, it was expected that the treatment period should be shortened to a fixed duration of 2 years for MB patients. However, at the beginning, many leprologists, especially those in the economically developed and well facilitated areas, were reluctant to terminate MDT treatment as a fixed duration, preferring to extend the treatment until a negative bacterial index was achieved, as advised by the National Leprosy Technical Conference in 1982, mainly because they feared that cure may not be complete and that the disease may relapse. From the present study, it was found that for patients treated with WHO/MDT-MB, there was no significant difference in the relapse rate between patients treated with the FD-MB and SN-MB regimens, the latter was even slightly higher than the former, which was comparable with the results in 8307 MB patients in selected areas in China ([10]). The slight difference between the two regimens in the present study should be further evaluated.

CONCLUSION

The results of the present national study noted that the relapse of leprosy after WHO/MDT is acceptably low and has not become a serious clinical or public health problem at present although it cannot completely reflect the ultimate situation of WHO/MDT relapse in China. This optimism can be sustained after the trend of relapse is further followed up, because it is known from the experience of DDS treatment that the average incubation period for dapsone-resistant relapse was as long as 15.8 years after commencing sulfone therapy ([17]), and it is expected that the relapse rates may increase in the future.

From the findings in the present study, it can be recommended that although the long-term follow up is not generally feasible in the present leprosy field program it is still necessary to recommend annual follow up for at least 5 years for PB and 10 years for MB patients after completed WHO/MDT in China in order to ensure that any

patient with relapse can be promptly detected for treatment and cease being a source for the continuing spread of the disease in the community. This consideration should be made when planning national policies for leprosy surveillance and consolidation of leprosy units, as well as the financial allocations for leprosy activities.

SUMMARY

Based upon the data from the Chinese National System for Leprosy Surveillance, this paper reports on the relapses in 47,276 leprosy patients cured by or released from WHO-recommended multidrug therapy (WHO/MDT). The overall relapse rate was 0.73/1000 patient-years (PY). There was a statistically significant difference in the relapse rates of WHO/MDT-MB (0.61/1000 PY) and WHO/MDT-PB (1.04/1000 PY) (χ^2 = 15.7, p <0.01) patients. For multibacillary (MB) patients, the relapse rate in patients treated with fixed-duration MDT (0.56/1000 PY) was comparable with that in patients treated with MDT until skin-smear negativity (0.73/1000 PY) (χ^2 = 2.20, p >0.05). Our present study suggests that fixed-duration MDT is a cost-effective regimen for the treatment of leprosy in China. The present results also show that relapse of leprosy is acceptably low and has not yet become a serious clinical or public health problem but, based upon the incubation of relapse in MDT patients, it is necessary to encourage annual follow up for at least 5 years for paucibacillary (PB) and 10 years for MB patients after being released from WHO/MDT.

RESUMEN

Basados en los datos del Sistema Nacional Chino para la Vigilancia de la Lepra, este articulo reporta la tasa de recaida en 47,276 pacientes con lepra curados con poliquimioterapia (PQT). La tasa global de recaida fue de 0.73/1000 pacient-años (PA). Hubo una diferencia estadisticamente significativa en las tasas de recaída entre los pacientes MDT-MB (0.61/1000 PA) y MDT-PB (1.04/1000 PA) (χ^2 = 15.7, p <0.01). Para Los pacientes multibacilares (MB), la tasa de recaida en los pacientes tratados con PQT de duración fija (0.56/1000 PA) fue comparable con aquella de los pacientes tratados con PQT hasta su negatividad bacilar en piel (0.73/1000 PA) (χ^2 = 2.20, p >0.05). Nuestros resultados sugieren que la PQT de duración fija es una terapia costo-efectiva para el tratamiento de la lepra en China. Los resultados también muestran que la tasa de recaida de la lepra es aceptablemente baja y no ha llegado a ser un serio problema clinico o de salud publica, aunque tomando en cuenta la incubación de las recaidas en los pacientes PQT, es recomendable mantener el seguimiento anual de los pacientes cuando menos duratne 5 años para los pacientes PB y hasta por 10 años para los pacientes MB.

RÉSUMÉ

Cet article, basé sur les données provenant du Système National Chinois de Surveillance de la Lèpre, décrit les rechutes chez 47 276 patients atteints de lèpre et soignés par ou ayant terminé leur polychimiothérapie (PCT). Le taux de rechute global était de 0.73/1000 personnes-par-année (PPA). Une différence statistiquement significative fut trouvée parmi les taux de rechutes observés chez les patients multibacillaires (MB)-PCT (0,61/1000 PPA) et paucibacillaires (PB)-PCT (1,04/1000 PPA) (χ^2 = 15.7, p <0.01). Le taux de rechute parmi les patients MB traités par la PCT à durée pré-déterminée (0,56/1000 PPA) était voisin de celui rencontré chez les patients MB traités jusqu'à ce que l'examen du suc dermique soit négatif (0,73/1000 PPA) (χ^2 = 2.20, p >0.05). L'étude présentée ici suggère que la PCT à durée pré-déterminée présente un bon rapport coût-efficacité pour le traitement de la lèpre en Chine. Cette étude montre également que les rechutes de lèpre restent dans les limites de l'acceptable et ne sont pas encore devenues un problème clinique sérieux ou de santé publique. Cependant, basé sur les temps d'incubation et de rechute des patients sous PCT, il est nécessaire d'encourager le suivi clinique annuel pour au moins 5 ans chez les patients PB, et 10 ans chez les patients MB, après l'arrêt du traitement de PCT.

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