

Tuberculosis control in remote districts of Nepal comparing patient-responsible short-course chemotherapy with long-course treatment

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SUMMARY

SETTING: A tuberculosis programme in hill and mountain districts of Nepal supported by an international non-governmental organisation (NGO).

OBJECTIVE: To evaluate under programme conditions the effectiveness of unsupervised monthly-monitored treatment using an oral short-course regimen.

DESIGN: In this prospective cohort study, outcomes for new cases of smear-positive tuberculosis starting treatment over a two-year period in four districts in which a 6-month rifampicin-containing regimen was introduced as first-line treatment (subjects) were compared to outcomes for similarly defined cases in four districts where a 12-month regimen with daily streptomycin injections in the intensive phase continued to be used (controls).

RESULTS: Of 359 subjects started on the 6-month regimen, 85.2% completed an initial course of treatment compared to 62.8% of 304 controls started on the 12-month regimen ($P < 0.001$); 78.8% of subjects and

51.0% of controls were confirmed smear-negative at the end of treatment ($P < 0.001$). The case-fatality rate during treatment was 5.0% among subjects and 11.2% among controls ($P = 0.003$). Among those whose status was known at two years, 76.9% of subjects were smear-negative without retreatment, compared to 60.9% of controls ($P < 0.001$).

CONCLUSION: In an NGO-supported tuberculosis control programme in remote districts of Nepal, patient-responsible short-course therapy supported by rapid tracing of defaulters achieved acceptable outcomes. Where access and health care infrastructure are poor, district-level tuberculosis teams responsible for treatment planning, drug delivery and programme monitoring can be an appropriate service model.

KEY WORDS: tuberculosis programme; short-course chemotherapy (SCC); patient-responsible therapy (PRT); treatment outcomes; poor access areas

BACKGROUND

Tuberculosis epidemiology and control in Nepal

Tuberculosis (TB) remains a major cause of morbidity and mortality in Nepal. The average annual risk of new infection or reinfection (ARI) is estimated at 2%, with higher rates in urban areas; 61% of those aged 15–45 are thought to be infected.¹ The annual incidence for all forms of TB has been estimated by different methods at 167 and 233 per 100 000 population.^{2,3} Based on the estimated mid-year population of 22.1 million in 1996, this represents 35–50 000 new cases annually. The prevalence of human immunodeficiency virus (HIV) infection, the most important risk factor for active TB following infection, was estimated in 1994 at 0.07% among adults aged 20–49, and is expected to rise to 0.25% in this age group

by the end of the decade. Among the 32 cases of acquired immune deficiency syndrome (AIDS) reported to September 1994, 75% had TB.⁴ Two HIV seroprevalence studies have been conducted among new smear-positive patients presenting to the National Tuberculosis Centre in Kathmandu: in 1993, none of 300 patients were HIV-infected; in 1996, four of 500 tested positive.⁵

In 1995, the Ministry of Health approved a five-year plan to strengthen TB services according to model programmes developed by the International Union Against Tuberculosis and Lung Disease (IUATLD) and currently promoted by the World Health Organisation (WHO).^{6,7} In Nepal today, services are provided through the National Tuberculosis Programme (NTP) in 70 of the country's 75 districts; five districts along the northern border with Tibet currently have

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no government TB services. In more than 20 districts, TB services are supported by bilateral agencies or international non-governmental organisations (NGO).⁴ As of May 1997, an oral 8-month short-course chemotherapy (SCC) regimen is used as first-line treatment in 40 districts, including all those supported by NGOs and bilateral agencies. In the 30 remaining districts with NTP services, a 12-month regimen containing streptomycin in the intensive phase is used.⁵

Study setting

The Britain-Nepal Medical Trust (BNMT), an NGO established in Nepal in 1969, currently provides TB services in eight contiguous hill and mountain districts of eastern Nepal with populations of between 100 000 and 200 000. At the time of the study, the combined population was 1.33 million (1991 census). The northern districts extend to the border with Tibet and the southern districts lie adjacent to the plains bordering India. One of the eight district centres is accessible by an all-weather road, three can be reached by roads that may become impassable during the monsoon, and four have an airstrip. Travel between most points is on foot and for many patients distance to the nearest health facility is measured in hours or days.

At the time of the study, health facilities in hill districts were limited to one district hospital and approximately 10 sub-hospital facilities, called health posts (HP). Although one or two medical officers are appointed to the district hospital, doctors may fail to take up their post, in which case care is provided by paramedics with various levels of training. Functional X-ray equipment is the exception in hill hospitals, and laboratory testing is generally limited to the microscopic examination of blood, urine and stool samples. Staffing levels at HPs are variable and in hill districts there are rarely more than four clinical staff; at remote HPs, a sole health worker or peon may be on duty.

A TB clinic financed by the BNMT is located inside or near the hospital in each district, and a hostel is available for patients receiving injections or too ill to return home. Each clinic is managed by a resident clinic-in-charge. Two clinic assistants spend up to 50% of their time visiting HPs according to a fixed monthly schedule. Each clinic has a home visitor and one or two support staff to assist with clinic activities and facility maintenance. All members of the district TB team are familiar with the basic aspects of case-finding and case-holding, including smear preparation, recommended doses of TB drugs, and the recognition and management of adverse drug reactions. Rules regarding minimum staffing and leave ensure that patients can always obtain a smear examination, collect drugs or seek advice. Although TB drugs are increasingly available in private pharmacies even in remote hill districts, most cases of TB diagnosed and treated during the period of the study were registered and followed by BNMT programme staff.

MATERIALS AND METHODS

In this prospective cohort study, subjects were enrolled from four districts where a 6-month rifampicin-containing regimen was introduced as the first-line regimen for new TB cases. Controls were enrolled from four districts where a 12-month regimen with streptomycin in the intensive phase continued to be used. We opted to allocate districts rather than individual patients to the two treatment arms, since regimens of different duration administered with a different intensity of supervision were being compared. Allocating patients to different regimens within a district would have disrupted routine programme activities and created artificial pressures on adherence. To minimise the problem of patients travelling to another BNMT service district to obtain SCC if it were not available in their own, we allocated the four most remote districts to SCC. Patients seeking medical services not available where they reside tend to travel south to the larger cities in the plains.

All cases of smear-positive pulmonary TB registered between April 1990 and April 1992 who were previously untreated or had taken anti-tuberculosis drugs for less than one month were eligible for inclusion. TB suspects who could produce sputum had three sputum samples examined, at least one of which was a morning specimen. Pulmonary TB suspects with sputum negative for acid-fast bacilli (AFB) were given a broad spectrum antibiotic and re-evaluated, usually within one month. The majority of new patients were diagnosed at the district TB clinic, although some patients were detected at HPs and referred to the clinic.

Until this study, new pulmonary TB patients in all eight BNMT service districts were started on the 12-month regimen of daily isoniazid (H) and thiacetazone (T) in a combined formulation, with daily streptomycin (S) in the 2-month intensive phase (2SHT/10HT). This regimen was the nationally approved first-line regimen and was used in public-sector facilities in the other eight districts of the Eastern Region. The intensive phase was extended for one month if the patient was still smear positive at two months, according to national guidelines.

Although SCC drugs were being used by some programmes in Nepal at the time of the study, there were no national SCC regimen guidelines. On the advice of a UK-based committee of TB experts, we selected a 6-month regimen of rifampicin (R), isoniazid and pyrazinamide (Z) in the 2-month intensive phase, followed by rifampicin and isoniazid for 4 months (2RHZ/4RH); the continuation phase was started regardless of smear status at two months. For most adult patients a combined formulation of 450 mg of rifampicin and 300 mg of isoniazid in scored tablet form was used throughout treatment.

The choice of SCC regimen was based on the as-

sumption of a low prevalence of primary drug resistance in BNMT service districts where local access to TB drugs had been largely limited to BNMT clinics. During the study period, drug sensitivity tests on cultures of sputum from a random sample of 89 smear-positive patients who reported no previous treatment showed one isolate resistant to isoniazid alone (1.1%), three resistant to rifampicin alone (3.4%), two resistant to streptomycin alone (2.2%), two resistant to both streptomycin and thiacetazone, and one isolate resistant to all drugs tested, namely rifampicin, isoniazid, streptomycin, ethambutol and thiacetazone. Two isolates were identified as resistant to thiacetazone only, but the significance of this finding is not clear since thiacetazone was rarely available in uncombined formulations.

A standard treatment card was completed for all patients started on TB treatment. For SCC patients followed at the district clinic, the first follow-up appointment was arranged for one month after the start of treatment. For patients whose follow-up was arranged at HPs, sufficient drugs were supplied until the next monthly 'TB day' at that HP. Apart from this adjustment to the fixed schedule of TB days at HPs, follow-up for SCC patients was at monthly intervals during the intensive and continuation phases, although patients could visit the district TB centre at any time. Most patients started on SCC returned home on the first day of treatment. Patients too ill to make the journey home remained at the hostel until well enough to be discharged.

Patients given the 12-month regimen were accommodated at the district hostel for the duration of streptomycin injections, which were given daily by clinic staff. At the time of the study, directly observed therapy (DOT) was not practised for the oral component of the regimen, a combined formulation of isoniazid and thiacetazone. Pill-taking was monitored but not directly supervised. During the continuation phase patients on the 12-month regimen were followed at monthly intervals.

Sputum samples were collected at two months, at three months for those who had failed to convert, then at five months and at the end of treatment. Treatment protocols called for patients to continue the prescribed regimen for five months despite positive smears if there was continued clinical improvement. The decision to start a second-line regimen before five months was made by the clinic-in-charge if no doctor was available for consultation. Patients whose regimens were changed before five months were not excluded from the trial.

Treatment outcome categories were defined as recommended by the IUATLD with some modifications to reflect the system of monthly follow-up.⁸ We defined as *smear negative* a patient who completed treatment and was AFB negative on sputum collected during the last month of treatment and on one previous

occasion; if no specimen was collected during the last month of treatment, a negative sputum collected during the two months following treatment completion was accepted. Since adherence to the last month of chemotherapy could not be monitored if patients did not present for follow-up after finishing treatment, *treatment completed* indicates a patient who completed at least five months of the 6-month regimen or 11 months of the 12-month regimen, but for whom no sputum was collected at the end of treatment. *Treatment failure* indicates a patient who remained smear-positive or who became smear-positive at month five or later during chemotherapy. *Died* was recorded for a patient who died of any cause during chemotherapy or within two months of interrupting treatment. *Default* indicates a patient who failed to collect treatment for more than two consecutive months before the last month of prescribed treatment but who had not left the district where treatment was started. *Lost* was recorded for a patient who had left the district before treatment completion and for whom vital or treatment status could not be determined. *Transfer* patients were those referred to a treatment centre in another district.

Staff were instructed to obtain smears on all patients who could be contacted between 23 and 26 months after the start of the initial treatment episode. The choice of a two-year follow-up period after treatment start rather than after treatment completion was operationally simpler and allowed inclusion of all patients regardless of the number and duration of episodes of treatment interruption. The categories for outcome at two years after treatment start were similarly defined with the following additions: *relapse* indicates a patient whose initial treatment outcome was *smear-negative* or *treatment completed* and who became smear-positive again within two years. *Return after default* was recorded for patients registered as *default* on their initial treatment episode, and who were smear-positive on restarting treatment.

Data were abstracted from patient records onto data collection forms in the field, and entered manually into a D-Base (Ashton-Tate) database programme at the BNMT head office in Biratnagar. Computer printouts of registration categories and outcomes were later cross-checked against patient records in the field. Reported two-year sputum results were only accepted if the result had also been recorded in the district sputum register, which was verified after the two-year follow-up period for the last enrolled patient had elapsed. Data analysis and statistical testing were carried out using Epi-Info software (Epidemiology Programme Office, Centers for Disease Control, Atlanta, Georgia, USA). Associations between outcomes and regimens were tested for significance using χ^2 analysis. A *P* value of less than 0.05 or a 95% confidence interval (CI) excluding 1.0 were accepted as evidence of statistical significance.

Table 1 Outcome of first treatment episode by initial regimen

| Outcome category | 6-month (%) n = 359 | 12-month (%) n = 304 | P value |
|---------------------|------------------------|-------------------------|---------|
| Smear negative | 283 (78.8) | 155 (51.0) | <0.001 |
| Treatment completed | 23 (6.4) | 36 (11.8) | 0.01 |
| Treatment failure | 13 (3.6) | 16 (5.3) | NS* |
| Died on treatment | 18 (5.0) | 34 (11.2) | 0.003 |
| Defaulted | 15 (4.2) | 38 (12.5) | <0.001 |
| Lost | 3 (0.8) | 12 (3.9) | 0.007 |
| Transferred | 4 (1.1) | 13 (4.3) | 0.01 |

* Not significant, $P > 0.05$.

RESULTS

Treatment completion and default

Of 361 new smear-positive cases registered in the four SCC districts, 359 (99.4%) were prescribed 2RHZ/4RH. In the four control districts, 304 (97.1%) of 313 new smear-positives were prescribed 2SHT/10HT. Treatment results according to IUATLD outcome categories are shown in Table 1. Of 359 new smear-positive patients started on the 6-month regimen in SCC districts during the 2-year enrolment period, 85.2% completed a course of anti-tuberculosis therapy during their initial treatment episode compared to 62.8% new smear-positive patients started on the 12-month regimen. The relative risk of default among patients started on the 6-month regimen was 0.33 (95% CI: 0.19–0.60).

Case fatality and treatment failure

Of the 359 patients started on the 6-month regimen, 17 (4.7%) died while on the prescribed regimen. This compares to a case-fatality rate of 9.9% (30/304) among patients taking the 12-month regimen. One patient started on the 6-month regimen and four patients started on the 12-month regimen died on treatment after their initial regimen had been changed. Overall, the crude relative risk of death on treatment for new smear-positive patients started on the 6-month regimen was 0.45 when compared to patients started on 12-month regimen (95% CI 0.26–0.78).

Treatment failure, or smear-positivity after month 5 of treatment, occurred among 3.6% of SCC patients and 5.3% of controls ($P = 0.30$). Treatment outcomes reported in Table 1 do not capture changes in regimen during the initial treatment episode, which are shown in Table 2. More patients on the 12-month regimen had their drugs changed because of failure to improve before five months, but did not fulfil the smear criteria for treatment failure. Other reasons for changing the 12-month regimen included refusal of injections, the substitution of an oral regimen to allow the patient to return home and, most importantly, adverse drug reactions.

Two-year outcome

The choice of a fixed two-year follow-up period after treatment start meant that the post-treatment follow-up for adherent patients completing the 6-month regimen averaged 1.5 years compared to an average of one year for patients completing the 12-month regimen. Table 3 shows the results of treatment at two years after treatment start. Two-year outcome results were available for 317 patients started on the 6-month regimen (88.3% of 359); of these, 76.9% were confirmed as smear-negative without retreatment. Among the 243 patients started on the 12-month regimen whose status was known at two years (79.9% of 304), 60.9% were smear negative without retreatment.

Table 3 can be read as the overall outcome at two years of comparable field programmes with different first-line regimens. While the proportion of patients relapsing within two years is lower for those started on the 12-month regimen, more patients starting the 12-month regimen had a change of regimen during treatment (18.8% versus 1.4%) and then went on to complete treatment. If the comparison of retreatment rates due to relapse within two years is restricted to patients who were confirmed smear negative after completing the initially prescribed regimen, then the proportion of patients resuming treatment within two years of starting the 6-month regimen was 6.3% (16/252), similar to 5.8% (6/103) for the 12-month regimen, despite a longer post-treatment follow-up period.

DISCUSSION

Findings and limitations of this study

The present study was designed to evaluate the impact on treatment outcome when a district-level TB programme in remote areas switched from a 12-month to a 6-month regimen. At the time the study was initiated, most public health and NGO-supported programmes were using the nationally recommended 12-month regimen. The most pressing operational issue

Table 2 Completion of initial regimen during first treatment episode

| Outcome category | 6-month (%) n = 359 | 12-month (%) n = 304 | P value |
|---|------------------------|-------------------------|---------|
| Initial regimen completed | 302* (84.1) | 147† (48.4) | <0.001 |
| Regimen changed due to drug intolerance | 3 (0.8) | 32 (10.5) | <0.001 |
| Regimen changed for other reasons | 2 (0.6) | 25 (8.2) | <0.001 |
| Treatment failure on initial regimen | 13 (3.6) | 16 (5.3) | NS‡ |
| Died on initial regimen | 17 (4.7) | 30 (9.9) | 0.01 |
| Defaulted, lost, transferred | 22 (6.1) | 54 (17.8) | <0.001 |

* 280 (78.0% of 359) confirmed smear negative.

† 121 (39.8% of 304) confirmed smear negative.

‡ Not significant, $P > 0.05$.

Table 3 Outcome at two years by initial regimen*

| Outcome category | 6-month (%) <i>n</i> = 359 | 12-month (%) <i>n</i> = 304 | <i>P</i> value |
|-------------------------------|----------------------------------|-----------------------------------|----------------|
| Alive without retreatment | | | |
| Smear-negative | 244 (68.0) | 148 (48.7) | <0.001 |
| No smear result | 2 (0.6) | 1 (0.3) | NS† |
| Retreatment started | | | |
| Initial treatment failure | 13 (3.6) | 16 (5.3) | NS† |
| Return after default | 7 (1.9) | 8 (2.6) | NS† |
| Relapse | 19 (5.3) | 7 (2.3) | 0.05 |
| Died before retreatment | 27 (7.5) | 40 (13.2) | 0.02 |
| Default without retreatment | 5 (1.4) | 23 (7.6) | <0.001 |
| Smear or vital status unknown | | | |
| Lost | 31 (8.6) | 32 (10.5) | NS† |
| Transferred | 4 (1.1) | 13 (4.3) | 0.01 |
| Not verified | 7 (1.9) | 16 (5.3) | 0.02 |

* Outcomes are grouped by the initially prescribed regimen and include patients whose regimen was changed. See text for the proportion of relapses among patients who completed the initially prescribed regimen. Not all patients recorded as 'default' in Table 1 could be traced at two years.

† Not significant, $P > 0.05$.

was how SCC could be effectively delivered to improve patient survival. We chose monthly monitoring since this was the standard follow-up period at public-sector facilities in Nepal when the study was carried out, and utilised the existing drug-delivery system to remote HPs according to a fixed schedule of monthly TB days.

We found that patients started on the 6-month regimen were more likely to survive and be cured and less likely to suffer adverse reactions that required a change in regimen; default was less common, and those who defaulted were more likely to restart treatment. Approximately 4% of smear-positive patients started on the 6-month regimen were treatment failures and 5% relapsed within two years of starting treatment. These rates of failure and relapse are higher than expected for patients fully adherent to a rifampicin-containing regimen where the prevalence of primary drug resistance is low and suggest that some patients took their drugs on an irregular basis, despite compliance with monthly follow-up.

The comparability of two-year outcome results in the two treatment groups is partly compromised by a differential loss to follow-up. Among patients started on the 12-month regimen, 20.1% had either been transferred during their initial treatment episode, left the district, or did not have their status assessed at two years, compared to only 11.7% among those started on the 6-month regimen ($P = 0.003$). Lower loss to follow-up in SCC districts may be partly attributable to the allocation of more remote districts to SCC, where patients may have been less likely to change residence. A second reason for better follow-up in SCC districts may have been the extra time available for programme staff to trace patients at two years,

because of the lower workload associated with the 6-month regimen.

Higher case-fatality and default rates during the initial treatment episode among patients started on the 12-month regimen may have been due to differential self-selection to BNMT services according to the regimen offered. Patients with more information on treatment options who resided in districts where the 12-month regimen continued to be used may have sought short-course drugs from private medical practitioners in adjacent districts to the south. In contrast, patients unaware of different treatment options, or too poor to seek private services, may have been more likely as a group to have poorer outcomes. Although this hypothesis is possible, we feel differential self-selection was minimal, since total patient numbers and outcomes remained stable after the trial when the 6-month regimen was introduced into the remaining BNMT service districts. Among 714 new smear-positive pulmonary patients registered in the eight service districts between April 1992 and April 1994, 602 (84.3%) completed a course of treatment, 515 (72.1%) were confirmed smear-negative, 40 (5.6%) died, 25 (3.5%) defaulted, 29 (4.1%) were registered as treatment failures and 18 (2.5%) were transferred to another district.⁹

Drug costs more than doubled in SCC districts, but in an NGO-supported programme with some expatriate staff these accounted for only 10% of overall programme costs, and total expenditure in SCC districts increased by only 9% per registered smear-positive case.¹⁰ Assuming that unknown outcomes in both SCC and control districts were comparable to known outcomes, the 9% increase in expenditures in SCC districts was associated with a 31% increase in the initial treatment completion rate (Table 1), a 26% increase in the proportion of patients who remained smear-negative at two years (Table 3) and a 48% decrease in death rates before retreatment at two years (Table 3).

The WHO currently recommends short-course regimens with four drugs supervised daily during the initial two months. In areas of low initial resistance, three drugs during the initial phase may be adequate, but the advisability of a three-drug intensive phase where DOT is not routinely applied may be in doubt. Since 1995, Nepal has adopted an 8-month SCC regimen containing ethambutol (E), with a four-drug intensive phase. This regimen (2RHZE/6HE) has been adopted in all districts where SCC is used.

A 4% treatment failure rate and a 5% relapse rate at two years using patient-responsible therapy (PRT) suggest that more intensive treatment supervision, including DOT, should be organised where possible. Since July 1996, all patients in one BNMT service district have been offered a choice of ambulatory DOT from a health facility or accommodation at the TB hostel in the district centre for the duration of the

rifampicin-containing intensive phase (M. Akhtar—personal communication). Only 45% of registered patients reside close enough to a health facility for ambulatory DOT; the remainder elect hostel accommodation. Since the BNMT hostel was constructed before 1990 when the 12-month regimen was the standard first-line treatment, accommodating new TB cases for DOT has not required capital outlay or placed pressure on hospital beds. However, the feasibility of facility-based DOT as a service delivery option where facility access is poor is open to question, and the incremental cost-effectiveness of accommodating patients compared to closely supervised PRT or community-based DOT needs to be evaluated.¹¹

CONCLUSION

In our setting, acceptable outcomes were achieved with patient-responsible SCC organised from a district-level clinic and using outreach staff to deliver drugs to patients through peripheral health facilities. Covering appropriate catchment populations, district teams are able to ensure quality-controlled microscopy, an uninterrupted drug supply and accurate record-keeping to monitor treatment outcomes. By having a small and stable group of appropriately trained persons responsible for programme activities, treatment protocols are adhered to, follow-up is regular and patients who interrupt treatment are quickly identified and traced. Other district programmes in remote areas of Nepal with NGO or bilateral agency support have shown comparable results using broadly similar delivery strategies.^{12,13}

When planning district TB services, account must be taken of patient access to facilities, TB caseloads and the capacity of staff in peripheral health facilities to assume managerial tasks. In remote areas of Nepal, as in other countries in South Asia, health facilities are characterised by chronic understaffing, frequent transfers of personnel and poor support from district public health offices.^{14,15} In these settings, it may not be an efficient management strategy to delegate the responsibility for treatment planning and monitoring to multi-purpose health workers, although they may be appropriate treatment supervisors for individual patients.

We feel that the outcomes observed using patient-responsible SCC in a remote setting in South Asia reflect sound management principles appropriate to the caseload and the health services context. Effective service strategies adapted to local circumstances are more likely where stable management teams are responsible for all programme components within an

appropriate catchment area and have the flexibility to innovate within a basic programme framework.

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R É S U M É

CADRE : Programme de lutte antituberculeuse soutenu par une ONG internationale dans des districts de collines et de montagnes au Népal.

OBJECTIF : Evaluation de l'efficacité d'un traitement de six mois, non supervisé mais contrôlé tous les mois dans des conditions du programme.

SCHEMA : Etude prospective de cohortes de nouveaux cas de tuberculose positifs à l'examen direct, mis sous traitement au cours d'une période de deux ans, avec comparaison de quatre districts où un régime de 6 mois incluant la rifampicine est introduit comme traitement de première ligne (les cas), et de quatre autres districts où le même type de cas est soumis à un traitement de 12 mois avec injections quotidiennes de streptomycine dans la phase initiale (les contrôles).

RÉSULTATS : Un traitement a pu être conduit à son terme chez 85,2% des 359 sujets soumis au régime de 6 mois contre 62,8% des 304 contrôles traités par le régime de 12 mois ($P < 0,001$). A la fin du traitement la négativa-

tion de l'examen direct est confirmée chez 78,8% des sujets et 51,0% des contrôles ($P < 0,001$). Le taux de létalité en cours du traitement est de 5,0% chez les sujets et de 11,2% chez les contrôles ($P = 0,003$). Parmi les sujets dont la situation est connue à 2 ans, on note un taux d'examens directs négatifs sans retraitement chez 76,9% des sujets et 60,9% des contrôles ($P < 0,001$).

CONCLUSION : Des résultats acceptables ont été obtenus dans un programme de tuberculose soutenu par une ONG internationale et conduit dans une région reculée du Népal, grâce à un traitement court pris en charge par le patient, accompagné d'une recherche rapide des sujets défaillants au traitement. Lorsque l'accès aux services de santé est difficile, les équipes de tuberculose basées au niveau du district et responsables de la planification du traitement, de la distribution des médicaments et du suivi du programme peuvent constituer un modèle approprié de service.

R E S U M E N

MARCO DE REFERENCIA : Un programa de control de la tuberculosis en distritos montañosos de Nepal, sostenido por una organización no gubernamental (ONG).

OBJETIVOS : Evaluar la eficacia en condiciones de terreno, de un tratamiento por vía oral de 6 meses, no supervisado, pero controlado mensualmente.

MÉTODO : En este estudio prospectivo de cohortes se compararon los resultados del tratamiento de casos nuevos de tuberculosis con baciloscopia positiva, puestos en tratamiento en un período de dos años en cuatro distritos, con un esquema de primera línea, de 6 meses, que contenía rifampicina (sujetos), con aquellos en casos del mismo tipo en otros cuatro distritos, tratados con un esquema de 12 meses con inyecciones diarias de estreptomycina en la fase intensiva (controles).

RESULTADOS : De los 359 sujetos que comenzaron el esquema de 6 meses, un 85,2% completó el tratamiento, comparado con el 62,8% de los 304 controles que comenzaron un esquema de 12 meses ($P < 0,001$); el 78,8%

de los sujetos y el 51,0% de los controles tenían una negativización confirmada de las baciloscopias al final del tratamiento ($P < 0,001$). La tasa de letalidad durante el tratamiento fue de 5,0% en los sujetos y de 11,2% en los controles ($P = 0,003$). Entre los casos cuya situación era conocida a los dos años, el 76,9% de los sujetos tenía baciloscopias negativas sin retratamiento, comparado con el 60,9% de los controles ($P < 0,001$).

CONCLUSIÓN : En un programa de control de la tuberculosis sostenido por una ONG internacional, en distritos remotos de Nepal, se obtuvieron resultados aceptables con un tratamiento de corta duración, bajo la responsabilidad del paciente, apoyado por una búsqueda rápida de los pacientes que abandonaban. En aquellos lugares donde el acceso a los servicios es difícil, los equipos de tuberculosis del nivel distrito, responsables de la planificación, entrega de medicamentos y manejo del programa, pueden constituir un modelo de servicio apropiado.