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Control of mucocutaneous leishmaniasis, a neglected disease: results of a control programme in Satipo Province, Peru

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Summary

Mucocutaneous leishmaniasis (MCL) is an important health problem in many rural areas of Latin America, but there are few data on the results of programmatic approaches to control the disease. We report the results of a control programme in San Martin de Pangoa District, which reports one of the highest prevalences of MCL in Peru. For 2 years (2001–2002), the technicians at the health post were trained in patient case management, received medical support and were supplied with antimonials. An evaluation after 2 years showed the following main achievements: better diagnosis of patients, who were confirmed by microscopy in 34% (82/240) of the cases in 2001 and 60% of the cases (153/254) in 2002; improved follow-up during treatment: 237 of 263 (90%) patients who initiated an antimonial therapy ended the full treatment course; improved follow-up after treatment: 143 of 237 (60%) patients who ended their full treatment were correctly monitored during the required period of 6 (cutaneous cases) or 12 (mucosal cases) months after the end of treatment. These achievements were largely due to the human and logistical resources made available, the constant availability of medications and the close collaboration between the Ministry of Health, a national research institute and an international non-governmental organization. At the end of this period, the health authorities decided to register a generic brand of sodium stibogluconate, which is now in use. This should allow the treatment of a significant number of additional patients, while saving money to invest in other facets of the case management.

keywords mucocutaneous leishmaniasis, prevalence, programme, evaluation, Peru

Introduction

Mucocutaneous leishmaniasis (MCL), caused by *Leishmania (Viannia) braziliensis*, is endemic in Peru and affects the populations living in the tropical rain forest in the eastern part of the Andes (Lucas *et al.* 1998). The initial lesion comprises a cutaneous nodular and infiltrative lesion frequently leading to ulceration with raised edges, which causes little pain and usually heals spontaneously (Davies *et al.* 2003). Diagnosis is based on directly evidencing the parasite in the lesions through microscopical examinations of Giemsa-stained smears (Dimier-David *et al.* 1991) and/or in demonstration the parasite in *in vitro* cultures and/or by PCR methods (Lopez *et al.* 1993). The standard treatment of these lesions is daily injections of pentavalent antimony for 20 days, available as either Pentostam® (sodium stibogluconate, GSK) or Glucantime® (meglumine antimoniate, Aventis) (Croft & Yardley 2002). In addition to being painful when administrated intramuscularly and relatively toxic, this treatment is very expensive (US$420 per course of treatment in Peru). Extensive and mutilating mucosal lesions may arise years after the healing of the primary cutaneous lesion. The mucosal lesions affect the upper respiratory tract and may lead to the destruction of nasopharyngeal cartilages and, consequently, to gross mutilation and disfiguration (Wijeyaratne *et al.* 1994). First-line treatment of the mucosal disease is a 30-day course of pentavalent antimonials at standard doses. Amphotericin B is the most widely used second-line treatment but the risk of severe adverse effects limits its use to hospital settings (Crofts 1976; Llanos-Cuentas *et al.* 1997). Because treatment efficacy with antimonials varies according with the severity of the disease (Llanos-Cuentas *et al.* 1997) and because relapses are not rare, a follow-up period of 12 months is warranted during which the evolution of the lesions is monitored. The most commonly

used follow-up schedule is review at 1, 3, 6 and 12 months after the end of treatment. Although MCL is generally neglected by researchers and funding agencies (Davies *et al.* 2003), limited efforts towards developing more effective, safe and appropriate treatments for this disease have been made.

According to reports by the Peruvian Ministry of Health (MOH), San Martin de Pangoa is the district most affected by MCL in the Satipo Province of Junin Department (Figure 1). In 1999, the prevalence of the disease was 339 cases/100 000/year, almost twice the average prevalence of 192 cases/100 000/year in the province (source of cases: UTES-Satipo). In December 2000, an assessment by Médecins Sans Frontières (MSF) using a convenience sample of 1096 persons, found 29 cases (13 cutaneous and 16 mucosal) considered as leishmaniasis based on the clinical characteristics and the history of the lesion, yielding a point prevalence of 2645 cases/100 000 inhabitants (Guthmann *et al.* 2000). The disease predominantly affected migrant agricultural workers who had moved to the area in recent years. These figures suggested that the prevalence of the disease was high in the general population of the district, and that a large number of patients remained untreated in the most remote and inaccessible areas of the region. Moreover, the assessment showed a number of deficiencies within the national leishmaniasis control programme, such as insufficient and poorly trained personnel and inadequate stocks of pentavalent antimonials to ensure the adequate treatment of

Figure 1 Area of the project (•).

all patients. In an effort to improve case management, control activities were strengthened and developed with participation of three institutions: the Peruvian MOH, the Institute of Tropical Medicine of Universidad Peruana Cayetano Heredia of Lima (IMT-UPCH) and MSF. In this paper, we report the results of this project 2 years after its initiation in January 2002.

Study area and brief description of the leishmaniasis control program

San Martin de Pangoa is a rural area of 32 642 inhabitants (2000 data) where the main economical activity is agriculture (coffee, cacao, citrus and wood). The population lives in small villages of a few hundred people, often isolated and inaccessible by car during the rainy season (December to March). Health care is provided through rural health posts that each serve several villages and are run by a health technician. The Leishmaniasis National Control Program relies on the work done by the health technician at the health post. Patients are first diagnosed clinically by the technician who makes a skin smear that is sent to the laboratory in San Martin de Pangoa town. Parasitologically confirmed cases are treated if drugs are available. The pentavalent antimonials are administered as daily injections by the health technician at the health post for 20 (cutaneous lesions) or 30 (mucosal lesions) days. Second-line treatment with amphotericin B is only available at the hospital level. The health technician is also responsible for the follow-up of patients during and after the course of treatment (6 months for cutaneous patients and 12 months for mucosal patients), completion of the registers and reporting to the central level. The activities of the health technician are not limited to leishmaniasis, but include 18 other programmes (malaria, tuberculosis, Expanded Programme on Immunization, etc.). The workload thus generally exceeds capacity, which leads to insufficient quality of the clinical diagnosis and of skin smears, poor supervision of patients under treatment, lack of follow-up after the end of the treatment and incomplete registration of patient records. Moreover, the work and efforts made by the health technicians are often not recognized by their supervisors. As the working conditions are far from ideal (low salaries, temporary contracts signed every month, lack of vacations, no health insurance, etc.), the technicians are often undermotivated and discouraged.

Objectives and activities

The general objective of the project involving these three institutions was to decrease morbidity caused by MCL through improved case management of patients in San

Martin de Pangoa District. The hypothesis was that by supporting the technician at the different stages of the case management process (diagnosis, treatment, follow-up and keeping patient records), his/her motivation would increase and the cycle no support–no motivation–low efficiency of work would be broken. Each of the three institutions involved in this project had a clearly defined role. The work was carried out by the MOH personnel (health and laboratory technicians), in each of the MOH facilities (17 health posts, one laboratory and one reference hospital at San Martin de Pangoa) with equipment and drugs given by the MOH when available. The IMT-UPCH gave technical support, participated in the training of health professionals and technicians, supervised the laboratory and was available for management of severe cases. MSF provided a support team of five persons (doctor, nurse, health technician, administrator and driver) whose main activities were: training of health technicians; transport of the skin smears to the laboratory; supply of medication for all leishmaniasis patients once the diagnosis was made; supervision of the overall activities and monthly reporting and statistical follow-up of cases. Six specific objectives were defined and for each of them specific activities were implemented and indicators were used to measure the results.

Case detection was improved. The health technicians were asked to perform weekly visits to the villages. A schedule was drawn up which included day of visit and name of village. Radio announcements informed the population in advance of scheduled visits. House-to-house and school visits were conducted during which persons were inspected and skin (and sometimes mucosal) lesions were identified. The population was informed about the clinical manifestations of the disease and asked to attend the health facility in case of suspicion of leishmaniasis.

Diagnosis was improved. At the health post level, health technicians were trained to identify and sample the skin and mucosal lesions. The lab personnel was re-trained in the staining and reading of the samples and the laboratory was supplied with the necessary equipment (microscope, reagents). A new sampling strategy was defined, incorporating a second skin smear (in case the first was negative) and the intradermal skin test (Davies *et al.* 1997). The following classification was used: a patient seen at the health post by the technician with a dermal lesion and a history of leishmaniasis was considered a suspected case of leishmaniasis; if the presence of the parasite was confirmed through skin microscopical examination, the patient was classified as a confirmed case of leishmaniasis; when this was not the case but the intradermal skin test was positive, he/she was classified as a possible case of leishmaniasis; all other patients for which the medical doctor considered that both the clinical lesion and the history were very suggestive of leishmaniasis were classified as probable cases of leishmaniasis. All leishmaniasis cases (confirmed + possible + probable) were treated.

Patients' access to treatment was improved through the supply of health posts with first-line drugs. Health technicians were trained to calculate the correct treatment dosage according to body weight and to adequately administrate the drugs.

The referral process of severe patients to second level structures was facilitated. Patient's follow-up was improved through the education of the patients and their families. Patients were looked for in their own villages when they did not report to the scheduled visits during follow-up.

Data reporting was improved. Health technicians were trained, new patient records were designed incorporating data to be recorded on follow-up, registers were completed monthly and kept up to date and regular reports were sent to the provincial health authorities.

Under the initiative of MSF, representatives of MSF in Peru, the Access to Essential Medicines Campaign of MSF, the MOH and other national institutions explored the possibility of making generic antimonials available as a way to reduce the cost of anti-leishmanial therapy.

Results

Number of cases detected

The number of suspected cases identified by the health technicians was 268 in 2001 and 326 in 2002, of which 240 (90%) and 254 (78%) were diagnosed as leishmaniasis cases (either confirmed, possible or probable) (Table 1). There were significant differences in prevalence between villages. Of the 494 leishmaniasis cases, 51 (10%) were mucosal: 12.1% (29/240) in 2001 and 8.2% (22/254) in 2002. Cases were reported throughout the year, with a peak beginning in June (Figure 2). Considering only the confirmed cases ($n = 82$ in 2001; $n = 153$ in 2002), the prevalence was 251 cases/100 000 in 2001 and 450 cases/100 000 in 2002, respectively 1.3 and 2.3 times higher than the year preceding the beginning of the project (193 cases/100 000/year in 2000).

Clinical and laboratory diagnosis

Of 240 cases diagnosed in 2001, 82 (34%) were confirmed cases for which the parasite was identified by microscopy, 26 (11%) were possible cases with a positive intradermal skin test and a negative microscopy, and 132 (55%) were

Table 1 Number of diagnosed cases (confirmed + possible + probable) and prevalence of leishmaniasis, San Martin de Pangoa District, Satipo Province, Peru, January 2001 to December 2002 (source: MSF, Ministerio de Salud)

	2001					2002				
		Cases			Prevalence		Cases			Prevalence
Villages	Population	Cut	Muco	Tot	rate*	Population†	Cut	Muco	Tot	rate*
Alto Kiatari	939	11	4	15	1597	955	7	1	8	837
Boca Kiatari	875	18	5	23	2628	890	6	4	10	1123
Campiruchiari	1302	7	1	8	691	1325	4	1	5	377
Chavini	1102	4	1	5	453	1121	1	0	1	89
Cubantia	995	5	0	5	502	1012	3	1	4	395
Fortaleza	499	10	0	10	2020	508	27	0	27	5315
Jerusalem M.	755	17	3	20	2781	768	10	3	13	1692
Matereni	1438	0	0	0	0	1463	1	0	1	68
Mazarun Quiari	1528	7	0	7	458	1554	0	0	0	0
Naylamp	1279	11	2	13	1016	1301	15	2	17	1306
San Antonio	1852	6	2	8	432	1884	3	1	4	212
San Cristobal	1094	7	0	7	640	1113	9	1	10	898
SJ Miraflores	1199	13	1	14	1167	1220	15	1	16	1311
SM Pangoa	5687	16	3	19	334	5785	22	2	24	414
San Ramon	4299	12	2	14	326	4373	10	1	11	251
SR de Alto Kiatari	708	10	1	11	1553	720	5	0	5	694
Tziriari	3340	32	3	35	1079	3398	53	1	54	1589
Union Chavini	1079	15	0	15	1390	1096	13	1	14	1277
Vilcabamba	1784	9	0	9	504	1815	9	1	10	551
Villa Maria	888	1	1	2	225	903	6	0	6	664
Rio Ene						855	13	1	14	1637
Total	32642	211	29	240	735	34059	232	22	254	745

* Number of cases per 100 000 population.
† The 2002 population was estimated using the Annual Growth Rate of 1.73% (source: INEI).

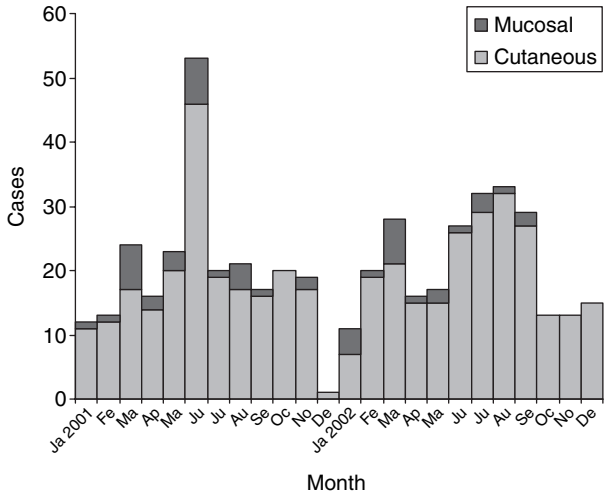

Figure 2 Distribution of diagnosed cases of leishmaniasis (confirmed + probable + possible) by month, San Martín de Pangoa District, Satipo Province, Peru, January 2001 to December 2002 (source: MSF, Ministerio de Salud).

probable cases (clinical lesion and history very suggestive of leishmaniasis) (Table 2). In 2002, the proportion of confirmed cases increased to 60% (153/254), possible cases remained stable (10%, or 24/254) and probable cases decreased to 30% (77/254).

Access of patients to treatment

Among the 494 leishmaniasis cases diagnosed in both years, 263 (53%) were treated with a pentavalent antimonial (110/240, 46% in 2001; and 153/254, 60% in 2002) (Table 2). The remaining cases (130 in 2001, 54%; and 101 in 2002, 40%) did not receive any therapy because they did not return to the health post and the team was not able to find the patient after the diagnosis had been made, sometimes even after visiting his/her village of residence. They were considered lost to follow-up before treatment and involved both mucosal and cutaneous cases (19 and 212 cases for the period 2001–2002 respectively). Nineteen of 231 (8%) cases who did not start antimonial therapy

Table 2 Number (%) of diagnosed cases of leishmaniasis (confirmed + possible + probable), treated and followed up, San Martin de Pangoa District, Satipo Province, Peru, January 2001 to December 2002 (source: AASF, Ministerio de Salud)

	2001	2002	Total
Suspected cases	268	326	594
Leishmaniasis cases	240	254	494
Confirmed	82 (34)	153 (60)	235 (48)
Possible	26 (11)	24 (10)	50 (10)
Probable	132 (55)	77 (30)	209 (42)
Lost to follow-up before beginning of treatment	130 (54)	101 (40)	231 (47)
Antimonial therapy	110 (46)	153 (60)	263 (53)
Completed	103 (94)	134 (88)	237 (90)
Lost to follow-up during treatment course	7 (6)	19 (12)	26 (10)
Follow-up after end of antimonial therapy			
Completed follow-up*	57 (55)	86 (64)	143 (60)
Lost to follow-up after end of treatment*	46 (45)	48 (36)	94 (40)

* The denominator for proportions is the number who completed the treatment, i.e. 103 in 2001, 134 in 2002 and 237 for the 2-year period.

were mucosal. They represented 231 of 494 cases (47%) for the period 2001–2002.

Patient follow-up during and after the treatment course

Among the 110 patients who were treated with antimonials in 2001, seven (6%) did not complete the full treatment course (30 days; all mucosal cases) because they interrupted their therapy despite tracing by the team in their villages. These were considered as lost to follow-up during treatment (Table 2). They represented 19 patients of 153 (12%) in 2002 (three of which interrupted the therapy because of secondary effects). Among the total number of 26 patients who did not complete treatment during the period, nine (34%) were mucosal. These represented 28% of the 32 mucosal cases who started treatment. A total of 237 patients (103 patients in 2001, 94%; 134 patients in 2002, 88%) completed the full treatment course (average of 90% over the 2-year period).

Of 103 patients who completed the full treatment course in 2001, 57 (55%) had a complete 6-month (cutaneous cases) or 12-month (mucosal cases) post-treatment follow-up. This percentage was 86 of 134 (64%) in 2002. The percentage of lost to follow-up after treatment was 45% in 2001, 36% in 2002 and 40% for the 2-year period. Among the 94 patients who were lost after treatment, 12 (13%) were mucosal. These represented 52% of the 23 mucosal cases who completed antimonial treatment.

Table 2 summarizes the general case management of leishmaniasis patients from clinical suspicion to the end of post-treatment follow-up. Of the 494 leishmaniasis cases diagnosed during the period 2001–2002, only 237 (48%) completed a full first-line treatment course with pentavalent antimonials, and only 143 (29%) were correctly followed from the day of diagnosis until the end of post-treatment follow-up. This low proportion of patients who were not correctly followed was particularly important for mucosal cases: of the 51 mucosal cases diagnosed, only 11 (21%) were correctly followed for a period of 12 months after treatment. Of the 143 patients correctly followed, 83 (58%) were considered cured at the end of follow-up, 51 (36%) were not cured and were still in follow-up, five (4%) were treatment failures, three (2%) had been referred to the hospital and one (1%) had died.

Treatment cost

When the current project was initiated, the MOH was using sodium stibogluconate (SSG, Viteco, Colombia) for the price of 17 soles (US$5) per vial of 1.5 g/5 ml (data: MOH). The drug cost for a full treatment course of a cutaneous patient (3 vials/day for 20 days) was therefore US$300 and closer to US$350–400 when additional costs (i.e. equipment and supplies) are taken into account (A. Llanos-Cuentas, personal communication). Following a proposal of MSF, the MOH agreed to include a generic SSG (from Albert David Ltd, India) in the list of critical drugs of the MOH. This inclusion should significantly reduce costs and increase access to treatment. According to MSF data (den Boer 2002; S. Lonlas, personal communication), estimated costs for the treatment of one cutaneous patient in Peru (including taxes and transportation) would be about one-sixth (approximately US$50) of costs before the beginning of the project.

Discussion

In the 2-year period, the objectives of the project were largely achieved. Considering only the confirmed cases of leishmaniasis, the number of patients increased threefold

between 2000 ($n = 63$) and 2002 ($n = 153$); the quality of the diagnosis improved, as shown by the significant and increasing proportion of leishmaniasis cases that were confirmed cases (34% in 2001, 60% in 2002); drugs were always available, allowing the complete treatment of every patient; the proportion of lost to follow-up during treatment (10%) was low; the proportion of patients who completed treatment and were correctly followed up during the required period of time after the end of the treatment was significant (60%). To our knowledge, this is the first published experience showing the achievements of a programme of detection, treatment and follow-up of leishmaniasis patients in Latin America.

We believe that these achievements are because of three major factors. First, to the resources that were put into this project by MSF during the two-year period: salaries of the team, rent of office and house, purchase and maintenance of a car, among major costs. Secondly, to the close collaboration between the three institutions involved, which permitted the mobilization of the leishmaniasis control programme at all its steps. Finally, the cornerstone was the constant availability of medications, which underlies all the rest: the health technician guarantees the patient that he/she will be always treated, and this creates a new and closer relationship between the patient and the care provider. Moreover, the patient suddenly realizes that the health service is now able to respond to his/her need, which had not been the case in the previous years when recurrent shortages of drugs left a significant number of patients without treatment. The general consequence of all this is an increased motivation of the health technician and an improved efficiency of his work (better diagnosis, better supervision, better reporting, etc.).

However, these achievements should not mask the real difficulties that persisted. The proportion of lost to follow-up before treatment was high (47%). Perhaps the lesions of many of these patients healed spontaneously and these people no longer felt the need to be treated. Additionally, as cutaneous lesions are only slightly painful, patients do not feel the need for medical consultation, especially as they are busy in the fields. They are not prepared to lose 20–30 days of work to walk to the health facility for the duration of a long and painful treatment. The proportion of losses was also high after treatment (40%), which may be explained by the socio-economic characteristics of the population in this area. The affected people live in villages isolated in the middle of the forest with poor access to transportation, making them very difficult to reach by the health workers, who are understaffed and overloaded by numerous tasks. The patients are usually migrant workers, who may stay in the forest only for a period of a few weeks or months before returning to their villages of origin without waiting for the results of the parasitological examination, or the end of the treatment (follow-up). The higher proportion of losses during and after treatment for mucosal compared with cutaneous cases could be explained by factors such as a the severity of the disease (patients may have travelled to the city or may have sought treatment in a hospital) and a worse prognosis (patients may have died) in mucosal cases, a longer treatment course in these patients (which could determine low adherence), or finally by socio-economic factors related to a more difficult access to health care, information that was not recorded in our setting.

New strategies should therefore be explored, for instance based on a network of health workers at the village level able to administer and supervise the treatment, and to ensure follow-up. The availability of rapid and easy-to-use diagnostics, and of efficacious, safe and especially shorter treatments that can easily be administered in local health centres, or be taken home by the patients, would be a major leap forward. For instance, a cheap and effective topical treatment for cutaneous leishmaniasis (possibly to complement with a short course systemic treatment) would represent a major advance in the control and management of this disease. Although there is still no strong evidence to support this hypothesis, combination therapies should increase the effectiveness of anti-leishmanial treatment in particular by decreasing the duration of the course and hence possibly its side-effects. Therefore, renewed research and development efforts are needed for improved and more appropriate treatments to specifically address the health needs of the affected population.

An important achievement of this project is the introduction of a generic brand of sodium stibogluconate (from Albert David Ltd) in the MOH list of critical drugs. This allows the importation into Peru and use of the cheaper generic antimonial drugs, like several other countries are already doing to increase access to this class of drugs. The treatment of the 494 patients diagnosed in the district during this 2-year period would have cost US$24 700 with the generic drugs (US$50/patient) instead of US$148 200 with currently used branded drugs (US$300/patient). If we consider the 8764 patients diagnosed in Peru in 2002 (MOH) and assume that all these patients had cutaneous leishmaniasis, the savings resulting from the use of a generic SSG would be US$2.191 million. This money could then be invested in salaries and training of more health workers to develop a better network for the early detection and follow-up of leishmaniasis cases at the village level.

As demonstrated in other countries, and in other diseases as well, the use of cheaper generic medications can dramatically contribute to improve access to an effective treatment, especially for the most impoverished

populations (CAME 2003; Laing *et al.* 2003). We believe that this is the way forward and that all actors, patients, health workers, NGOs and international organizations should advocate for the use of generic medications, while simultaneously call for needs-driven research and development for more appropriate drugs to tackle the needs of neglected populations. Government should base their drug policy on the effective use of these cheaper medications, and use the budget saved to invest in support or strengthening programmes such as the one implemented in Satipo.

Conclusions

The work of these three institutions in collaboration permitted a considerable improvement in the case management of patients affected by leishmaniasis in San Martin de Pangoa District, Peru. The registration of a generic pentavalent antimonial should allow the treatment of a significant number of additional patients, while saving money to invest in other facets of the case management. Difficulties encountered highlight the need to further strengthen the programme, particularly through improved case finding and follow-up of patients. Better treatments are also needed (more effective, safer, shorter and more easy to use). We believe this experience is important both because of its strategy and results, which are of interest for institutions and health services involved with this disease that afflicts the world poorest population and is so much neglected by donors.

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