LEISHMANIASIS CONTROL STRATEGIES

A CRITICAL EVALUATION OF

IDRC-SUPPORTED RESEARCH

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Leishmaniasis control strategies

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Leishmaniasis control strategies: A critical evaluation of IDRC-supported research

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Adapting Leishmaniasis Treatment to Peripheral Health Centers and Communities

By
Carlos Rojas[3]

Introduction

Rural health posts represent the first level of formal medical care, and the majority of patients make their first contact with the health authorities at this level. Their geographical location and the personnel that staff such posts helps give them an informal character which represents an important starting point in the interaction between the community and the formal health care system.

The implementation of health care at this level has optimized the efficiency of measures such as oral rehydration and the treatment of infectious disease. The participation of community health workers in diagnosis and treatment is increasingly important, particularly as related to acute respiratory infections (1) and tuberculosis (2). The involvement of mothers' groups in self-care of family and community health is another notable example of community participation (3).

Treatment of Leishmaniasis

At present the drug of choice for treatment of all leishmaniases, with the exception of the diffuse cutaneous form (DCL), are the pentavalent antimonials (4). Two formulations are available, (i) meglumine antimoniate and (ii) sodium stibogluconate, of which the former, marketed commercially as "Glucantime", is most used in the Americas. The drug is supplied in 5 ml ampoules, each containing 85 mg/ml of pentavalent antimony (Sb^{5+}), and is administered intramuscularly (IM) or intravenously

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(IV). The dose recommended by the World Health Organization is 20 mg of Sb^{5+} per kilogram body weight per day, divided into two injections. The maximum recommended adult dose is 850 mg, i.e., 2 ampoules (5). Leishmaniasis treatment is administered until clinical cure of lesions is achieved in cutaneous forms or parasitological eradication demonstrated in mucocutaneous or visceral forms of the disease. The average duration of treatment is 4 weeks, although this varies.

Availability of Treatment

In Colombia, glucantime is obtained through the government from national or foreign laboratories. The quantity provided to each hospital is dependent on the number of cases registered with the Ministry of Health, the official body concerned with distribution of the drug.

Patients diagnosed as having leishmaniasis generally are admitted to the local hospital for treatment, either by the local primary health post or community volunteer. The patients access to these local hospitals for diagnosis and treatment is limited by several factors, the most important of which are distance, travel costs (transport, food and lodging) and reluctance or inability to take time off from work. Ignorance of the potential consequences of leishmaniasis and belief in folk remedies are other limiting factors (Fig. 1). The consequences of this are as follows:

1. Late consultation and diagnosis may result in chronic, extensive and disfiguring lesions (Cutaneous leishmaniasis-CL); mucosal involvement (Mucocutaneous leishmaniasis-MCL); and general malaise and death (Viseral leishmaniasis VL).

2. Irregular treatment due to non-attendance of the patient at the health care center may prolong the curative process, increasing discomfort, toxic side-effects and greater cost as greater quantities of the drug are needed to counter irregularity of application. As these factors increase, "compliance" of the patient may fall correspondingly, resulting in the total abandonment of treatment.

3. Increased diagnostic costs. The parasitological tests used in the etiological diagnosis of chronic cases are more sophisticated and costly than standard methods (6).

Adaptation of Treatment to the Local Health Post Level

The advantages offered by diagnosis and treatment of leishmaniasis at local health posts are shown in chart 1. The ready access to such facilities allows patients to be treated on a frequent and regular basis. This lowers the costs of diagnosis and treatment as well as the expense to the patients themselves. The duration of treatment is reduced and patient compliance increased. Early treatment limits the severity of the disease and reduces the risk of complications. Community awareness and participation are also increased.

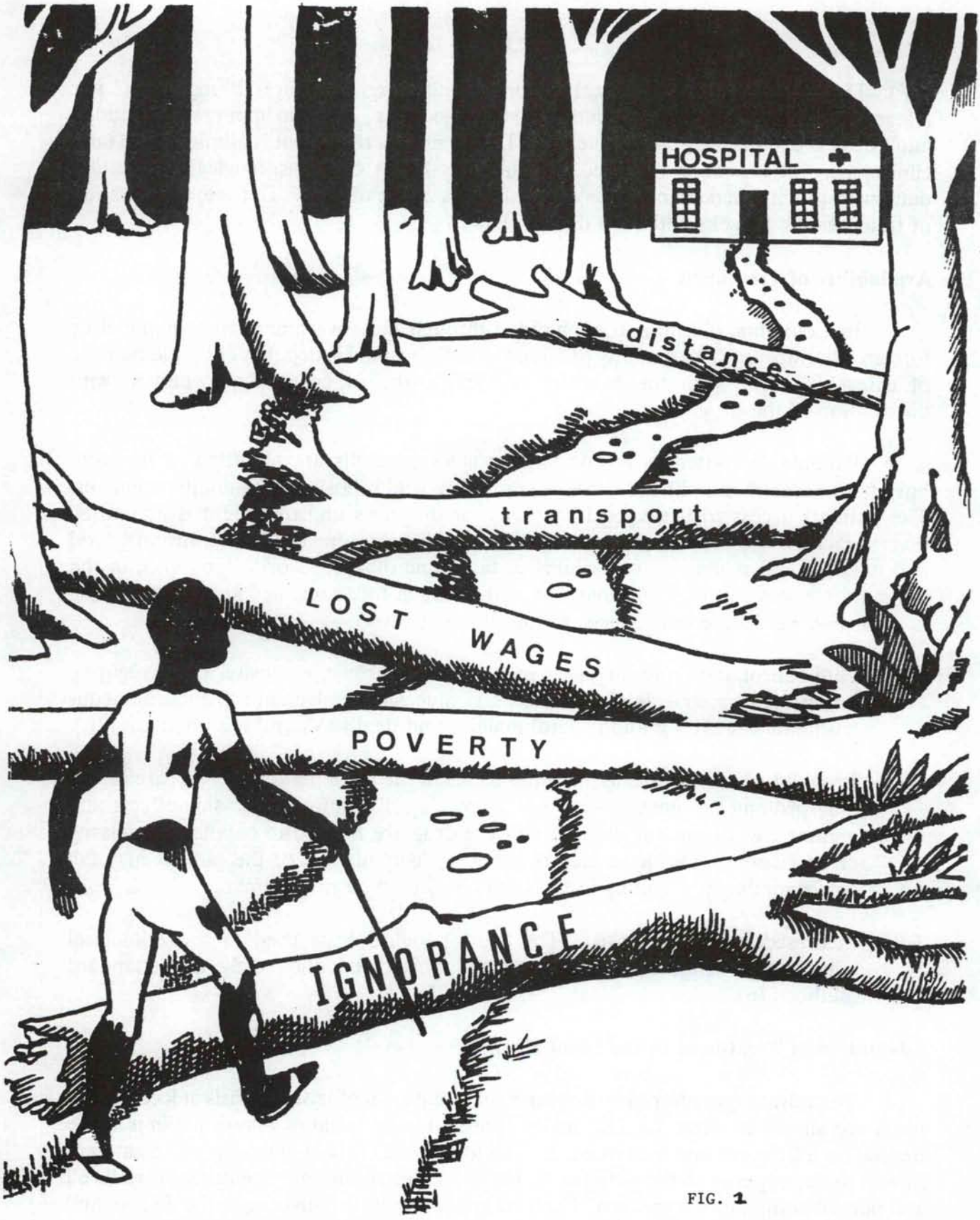
HOSPITAL
distance
transport
LOST WAGES
POVERTY
IGNORANCE

FIG. 1

CHART 1

ADAPTATION OF TREATMENT AT THE LEVEL OF LOCAL HEALTH POSTS: ADVANTAGES

Variables	Treatment	
	Hospital	Health Post
Early detection of cases	low	↑
Costs (government and patients)	high	↓
Compliance	low	↑
Duration of treatment	prolonged	↓
Morbidity (severity)	high	↓
Community participation	low	↑

Obstacles

We believe the main existing obstacles to the the adaptation of leishmaniasis treatment in local health posts are related to three aspects: diagnosis, treatment and administrative factors.

1. Diagnosis

The symptoms produced by visceral leishmanisis are not sufficiently specific to differentiate it from malaria and other generalized infections, while lesions due to cutaneous leishmaniases present a wide spectrum of clinical forms and may resemble other pathologies. In mucocutaneous leishmaniasis patients, the presence of a scar as a result of a primary cutaneous lesion may serve as an indicator for diagnosis.

The criteria for clinical diagnosis of leishmaniasis vary considerably according to the region, the parasite and the expertise of the health workers carrying out the diagnosis, so it is difficult to define general diagnostic guidelines. The identification and isolation of the parasite (parasitological diagnosis) is the only way to confirm a diagnosis of leishmaniasis. The most sensitive methods require a health care infrastructure and trained personnel and as such are expensive, beyond the normal resources of any local health post. While certain parasitological techniques can be applied to local health care posts these tend to be much less sensitive and specific (7).

2. Treatment

There are variations at the local level in the amounts of glucantime administered to patients. Smaller doses than those recommended by the WHO are often applied, giving subtherapeutic levels that prolong treatment and worsen the patient's condition. The reasons for this include ignorance of the correct dose required, insufficient availability of glucantime and discomfort of the patient caused by the injections. On the other hand, even glucantime therapy administered according to WHO guidelines presents certain problems: multiple doses over a prolonged period are required; the drug must be applied parenterally by qualified personnel; the risk of viral infections acquired from re-used syringe needles; and the sometimes incapacitating effects of the treatment. Each of these factors lower "compliance" of the patient. Glucantime therapy is also costly. Treatment of an adult with cutaneous leishmaniasis requires an average of 50 ampoules at a total cost of $150 US, not including other medical expenses.

3. Administrative aspects

Communities affected by leishmaniasis have had little or no participation in the diagnosis or treatment of the disease up to the present time. These activities have traditionally been performed exclusively in local hospitals which have rarely sought more active participation from the communities they serve. In many places the diagnostic and

treatment program is governed by the availability of glucantime and is performed in an improvised or disorganized manner. The absence of technical guidelines has impeded the standardization of diagnostic methods and treatment up to the present time.

A great many of the medical and paramedical personnel assigned to Leishmania-endemic areas have little prior experience of leishmaniasis and lack fundamental knowledge of its diagnosis and treatment. At present only those patients who arrive at the hospital receive glucantime therapy (passive detection), and many more who have no access to health care go without treatment.

In spite of the fact that leishmaniasis in Colombia is a disease that by law has to be registered, many cases still go unreported and the true incidence of the disease is probably much higher than estimated. Under registration of cases by medical personnel unaware of its importance is one reason why hospitals often lack adequate supplies of glucantime, cost being another factor. Diagnostic and treatment programs for leishmaniasis have lacked a separate budget in the past, forcing them to compete with other health problems accorded greater priority.

Search for Solutions

1. Administrative aspects

Efforts should be geared towards the creation of a level of primary health care for leishmaniasis patients. This should be readily accessible to patients and ensure that they receive prompt and adequate treatment. An infrastructure exists in most countries for primary health care, with trained medical and paramedical staff available to treat leishmaniasis patients. This reduces the costs of a leishmaniasis control program.

A specific budget should be set aside to cover administrative overheads as well as the costs of parasitological examinations, active search for cases and education programs related to leishmaniasis. An interesting alternative would be to allow health posts to receive glucantime directly from the manufacturers at a reduced price, and to allow them to distribute the drug within their areas as necessary. Government support for these measures is important but the willingness of local communities to participate, and their capacity to organize, propose solutions to their health problems and take responsibility for the consequences are probably more important.

2. Diagnosis

Sensitive, inexpensive and simple diagnostic methods should be developed and adapted to local conditions for use by trained paramedical personnel. The establishment and standardization of clinical criteria for the diagnosis of different forms of leishmaniasis would facilitate the work of paramedical staff and health volunteers in the detection and treatment of the disease, as would the development of protocols and clinical tools that can be used in health posts.

Implementation of certain parasitological diagnostic methods is already feasible from the technical point of view. Nevertheless, the ability of health workers in particular communities to implement and perpetuate these techniques should be ascertained.

The early detection of suspected cases of leishmaniasis and their referral to health posts is a task that can be fulfilled by the community. Development of clinical and parasitological screening methods for use by paramedical personnel is another priority requirement.

One instrument (the prediction rule) that was developed by CIDEIM researchers to permit the diagnosis of American tegumentary leishmaniasis (ATL) in endemic areas where parasitological diagnostic methods are not possible. An evaluation and categorization of a series of clinical and epidemiological variables in the patient, allowing a conclusion, is expressed as a final score. If this score exceeds a certain threshold value the probability that the patient has ATL is very high.

The rule was developed from studies of a group of patients, most of them from the Pacific Coast of Colombia, of which 100 had ATL confirmed by parasitological methods and 38 displayed other etiologies. The variables that were finally selected to develop the rule were:

1. Physical examination
   * type of lesion
   * lymphadenitis
   * trophic changes

2. Clinical history
   * history of trauma
   * origin in endemic area

3. Intradermal Montenegro test

Results in the group used to develop the rule were: sensitivity 96%, specificity 92% and efficiency 95%.

To validate the usefuleness of the rule a second population was evaluated, of which 123 patients had ATL and 35 some other etiology. Results here were: sensitivity 96%, specificity 70% and efficiency 87%.

These first results indicate that the prediction rule allows the detection of ATL patients without recourse to parasitological tests. The rule is an instrument that can be used by paramedical personnel and health volunteers.

3. Treatment

Most problems related to the treatment of leishmaniasis are concerned with glucantime. Efforts should be made to seek a better method of treatment. In the long term this method should satisfy the following criteria:

* Efficacy equal to or better than the pentavalent antimonials
* Administered orally
* Only one dose required
* Free of unpleasant side effects
* Inexpensive
* Does not require medical supervision

In the short term, several promising alternatives are available, notably the intralesional application of glucantime. The advantages of this treatment are: less drug and fewer contacts with patient are required, reduced adverse and toxic side effects, increased compliance of patients, and reduced cost of treatment

The disadvantages are as follows:

* Still requires trained personnel
* As yet no clinical trials have demonstrated a greater effect than standard IM or IV application
* No studies have demonstrated efficacy in the treatment of cases where there is a risk of systemic involvement

Conclusions

Leishmaniasis is a disease that mainly affects rural inhabitants who have limited access to treatment by trained personnel. Thus, the adaptation of methods of diagnosis and treatment to health posts is crucial for early and adequate management of the disease. While government involvement is important, active participation of affected communities is essential.

At the local level, the critical points in achieving early, accurate diagnosis, complete treatment, and the effective administration of resources for leishmaniasis control should be identified. Strategies and methods can then be tailored to meet the priorities of local communities, which are necessarily increasingly involved in the decision-making process.

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DISCUSSION SUMMARY

Dr. J. Chang pointed out that in Peru, the high cost and scarcity of antimony resulted in the use of alternative therapies of unproven benefit. Even in the case of antimony treatment, there was a high incidence of inadequate dosing. The reasons for non-compliance are certainly complex, but not the least of these would includes patients selling at least a portion of their allotment of drug for economic gain. This leads directly to the recommendation for better training of local health workers and more rigorously supervised chemotherapy. The larger question of course is when and under what conditions should drugs be put in the hands of the community? Overall, it seemed clear that if adapting leishmaniasis treatment to peripheral health centers and communities was to be successful, there is a need for more sophisticated local, rural health units where appropriate supervision, education and training can be provided.

Dr. Carlos Rojas stated that in general, antimony remains the drug of choice for all forms of leishmaniasis. Nevertheless, echoing the comments of Dr. Chang, complicated distribution schemes for getting drug to the patient, results in delayed treatment which may contribute to disease complications and ultimately more difficult and costly treatment. His comments again seemed to stress the same theme as Dr. Chang is asking how can we avoid having to bring the patient to the hospital and accomplish diagnosis and treatment at the local health post. To achieve these goals there is a need for trained personnel and technology for both diagnosis and treatment. No quick, easy solutions were offered, but it was clear that a consensus was present that a priority should be to move things to the level of the rural health post.