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A cross-sectional study on sociodemographic, clinical, and therapeutic characteristics of a pediatric population with cutaneous leishmaniasis

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ABSTRACT

Objective: To characterize the pediatric population with cutaneous leishmaniasis treated at a research center and to determine the therapeutic response and safety of the treatment.

Methods: A cross-sectional study was designed, in which data related to sociodemographic information, history of leishmaniasis, clinical characteristics, treatment, therapeutic response and adverse events were collected from the review of the clinical records.

Results: The analysis was conducted in 156 pediatric patients with median age of 10.5 (6-14) years. Regarding clinical and therapeutic characteristics, the lesions in these patients were mostly single ulcers, primarily located on the upper and lower extremities. A total of 114 patients were managed at Programa de Estudio y Control de Enfermedades Tropicales (PECET), and 26 of them received more than one treatment. Upon administration of the first therapeutic option, intralesional meglumine antimoniate had a cure rate of 43.18% (19/44 patients), followed by systemic meglumine antimoniate with a cure rate of 40% (8/20) and topical investigational medication with a cure rate of 25% (5/20). The most frequent adverse events were: arthralgia and myalgia for systemic meglumine antimoniate; nausea and vomiting for miltefosine; and local pain, edema, erythema and rash for topical treatment.

Conclusions: Although more prospective studies are needed to generate evidence-based recommendations and management protocols, miltefosine appears to be a favorable, safe and well-tolerated therapeutic option for the pediatric population. Despite the high percentage of loss to follow-up, the success achieved in pediatric patients with local treatments suggests that local therapies could also be considered for managing this condition in this population.

KEYWORDS: Cutaneous leishmaniasis; Pediatric population; Systemic treatment; Local treatment; Combined treatment; Tropical neglected disease; Safety; Therapeutic response

Summary

Question: What is the epidemiologic and clinical profile of the pediatric population with cutaneous leishmaniasis, and what is the therapeutic response and safety of the treatments received?

Findings: 156 clinical records were reviewed. 144 patients (73.1%) received treatment. The most common treatments leading to cure were intralesional meglumine antimoniate (43.2%) and systemic meglumine antimoniate (40%). Side effects depended on the treatment: systemic treatments: joint and muscle pain; topical treatments: swelling, pain, or rash.

Meaning: Results suggest that local treatments could be a better option for children. Miltefosine also seemed to be safe and well-tolerated. More studies are needed to confirm these results and improve treatment guidelines.

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1. Introduction

Cutaneous leishmaniasis (CL) is the most common clinical form of the disease and is widely distributed in regions of East Africa, North Africa, West and Southeast Asia, and the Americas, with special concentration in Brazil, Colombia and Peru[1]. In the specific case of Colombia, this clinical form accounts for 95%-98% of all cases[2]; the vector that transmits it is mainly found in tropical rainforest areas, which is why the disease mostly affects rural populations and individuals who visit these areas[3]. Although this disease primarily affects adults of working age, children are also at risk. For example, in 2020, 10% of the new cases of CL reported in the country were children under 10 years of age[4].

In Colombia, the first-choice treatment for CL in minors is miltefosine, followed by pentavalent antimonials (Glucantime®) as the second option. These recommendations are based on studies conducted in adults; however, therapeutic management in the pediatric population presents challenges, particularly regarding dose adjustment, safety profile, tolerability, routes of administration, immune response, and pharmacokinetic and pharmacodynamic response[5,6]. In addition, ethical and safety limitations in many cases prevent the inclusion of children in clinical trials, resulting in a limited amount of scientific evidence to guide evidence-based therapeutic management for this population.

Therefore, the objective of the study was to characterize the pediatric population with CL treated at the Programa de Estudio y Control de Enfermedades Tropicales (PECET, Medellín, Colombia), a specialized research center, and to determine the therapeutic response and safety of the treatment received.

2. Methods

2.1. Ethics

The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and Resolution 8430 of 1993 of the Colombian Ministry of Health. According to these guidelines, this type of research is considered risk-free. In addition, the confidentiality of the participants' identification data was guaranteed, and only the healthcare team involved in the study had access to the information.

Since the data analyzed were obtained from the medical records of minors attended at PECET, and in accordance with the provisions of Colombian resolution 1995 of 1999, which establishes standards for the management of medical records, the use of the data contained in them is permitted for healthcare personnel. Additionally, the representatives of the minors authorized the use of the information by completing the informed consent form (ICF) for patient care

(current version for each date of attention) at the research center. The different versions of the ICF had been approved by the safety committee of the site.

2.2. Data collection

A descriptive cross-sectional study using secondary data was conducted, in which information was collected from all patients under 18 years of age with a diagnosis of CL who were treated at PECET between January 2012 and December 2022.

A form designed for the study included information related to sociodemographic characteristics, history of CL, clinical characteristics of the lesions, diagnosis, treatment, therapeutic response and reported adverse events. The information was collected independently by two researchers from the children's medical records. In case of any discrepancies in the data, the information was validated directly from the source document, and the necessary corrections were made.

2.3. Outcomes and treatments

To harmonize the information, the outcomes of therapeutic response were defined based on the definitions established by the Pan American Health Organization (PAHO)[7], as follows:

Cure: Healing with complete reepithelialization and flattening of the lesion borders, disappearance of the induration at the base, resolution of lymphangitis (if detected) and absence of new lesions 3 months after completion of the treatment.

Clinical improvement: A patient who shows improvement of lesions 45 days post-treatment but does not complete follow-up at 3 months, so it cannot be defined as a cure.

Relapse: Defined as the reactivation of a healed lesion, regardless of the time of observation.

Therapeutic failure: When there is no clinical cure after receiving a complete course of treatment within 3 months.

Follow-up loss: A patient who drops out the therapeutic regimen or stops attending follow-up appointments after completing treatment, resulting in an unknown outcome.

The selection of therapeutic alternatives was based on the patient's clinical characteristics, the availability of the drug, and the conditions of the healthcare service; the therapeutic regimens were categorized into systemic and local.

Systemic therapeutic schemes include:

- Meglumine antimoniate, at a dose of 20 mg/kg/day/ intramuscular for 20 days, maximum 15 cc per day.
- Miltefosine at doses of 1.5 -2.5 mg/kg/day, orally for 28 days.
- Pentamidine at a dose of 150 mg every 2 days for 4 doses.

The following alternatives were used for the local regimens:

- Intralesional meglumine antimoniate, dosage depending on the size of the lesion.

- Topical amphotericin B, application 3 times a day for 4 weeks.
- Thermotherapy with electrode at 50 °C, usually a single session.
- Topical application of a drug in research every 8 hours for 40 days.

2.4. Statistical analysis

Data were organized and collected using Microsoft Excel and analyzed by the SPSS Statistics Software (version 29, IBM Corp., Chicago, IL). Categorical variables were described using relative and absolute frequencies. Quantitative variables were presented using the median and interquartile range (median, IQR). Finally, the *Chi*-squared test was used to explore the association between the type of treatment and its therapeutic response. A value of $P < 0.05$ was considered significant.

3. Results

156 patients under the age of 18 were included in this study. They were diagnosed with CL and received medical treatment at PECET (Figure 1).

3.1. Patient characteristics

Median age of the included patients was 10.5 (6-14) years. Pathological, sociodemographic, and clinical history data are presented in Table 1. For this population, we found that most of the children were male (57.69%, $n=90$), with a median of 10.5 years, and the 50% were between 6 and 14 years old.

Table 1. Sociodemographic characteristics and leishmaniasis history of the study population.

Variable	n (%)
Sex	
Female	66 (42.30)
Male	90 (57.69)
Age, years	
0-5	38 (24.35)
6-10	40 (25.64)
11-15	52 (33.33)
16-18	26 (16.67)
Possible infection Colombian Department	
Antioquia	129 (82.69)
Bolívar	1 (0.64)
Caldas	11 (7.05)
Chocó	4 (2.56)
Córdoba	1 (0.64)
Santander	3 (1.92)
Tolima	1 (0.64)
Venezuela*	2 (1.28)
No data	4 (2.56)
Possible infection area	
Rural	118 (75.64)
Urban	6 (3.85)
No data	32 (20.51)
Leishmaniasis personal history [#]	
Yes	29 (18.59)
No	76 (48.72)
No data	51 (32.69)
Cutaneous leishmaniasis previous treatment ^{&}	
Intralesional meglumine antimoniate	2 (1.28)
Systemic meglumine antimoniate	24 (15.38)
Miltefosine	1 (0.64)
No data	2 (1.28)
Not previously treated	127 (81.41)

*Cases from Cojedes and Yaracuy states, Venezuela; [#]leishmaniasis personal history refers to whether the child had a previous case of infection by *Leishmania* spp. prior to the one at the time of admission to PECET; [&]cutaneous leishmaniasis previous treatment refers to whether the patient received therapeutic management prior to his admission to PECET.

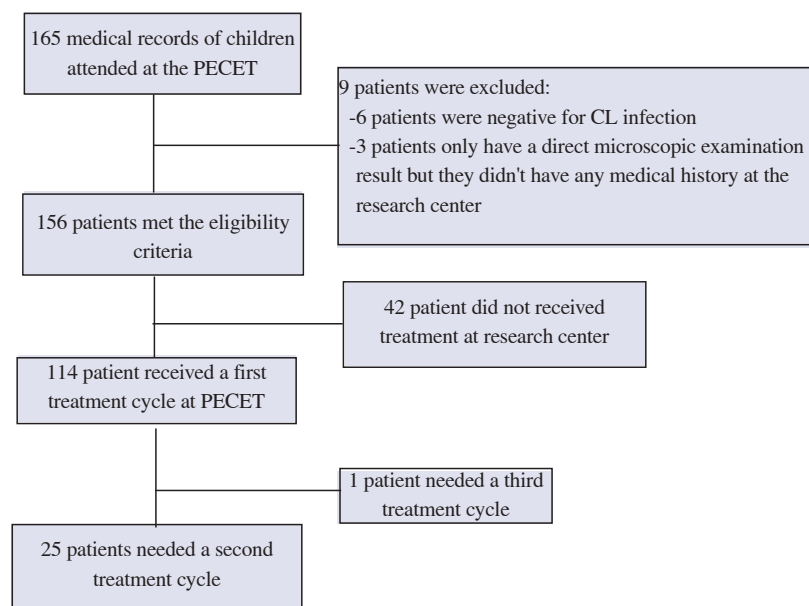


Figure 1. Patient selection process flowchart. PECET: Program for the Study and Control of Tropical Disease, CL: cutaneous leishmaniasis.

Regarding the origin of the CL cases, 82.69% (129/156) were from the department of Antioquia, while the remaining cases coming from other Colombian departments. Two patients (1.28%, 2/156) reported two states in Venezuela as the possible place of infection. Additionally, 75.64% (118/156) lived in rural areas. In relation to CL history, 127 patients (127/156, 81.41%) did not have a previous CL infection. Twenty-nine children (18.59%) reported a previous CL infection. Of these, 24 (15.38%) received systemic meglumine antimoniate as therapy before they were treated at PECET (Table 1).

3.2. Infection description and management

With respect to the current infection, the characteristics of the children's lesions were analyzed. In terms of type, number, and anatomical location, the more frequent lesions were ulcerated lesions (41.66%, 65/156), single lesions (43.59%, 68/156), and those predominantly located on the upper limbs (21.75%, 34/156) and lower limbs (17.95%, 28/156), respectively. When the time between lesion onset and diagnosis was evaluated, we found that most the patients had lesions with up to 15 weeks of progression (84/156, 53.85%) (Table 2).

Table 2. Lesions description of the study population.

Variable	n (%)
Type of lesion	
Ulcerated	65 (41.66)
Nodule	6 (3.85)
Scab	0 (0.00)
Wart type	3 (1.92)
Papular	0 (0.00)
Combined	6 (3.85)
Unspecified	76 (48.72)
Lesion number	
1	68 (43.59)
2	22 (14.10)
3	9 (5.77)
4	2 (1.28)
≥5	11 (7.05)
No data	44 (28.20)
Anatomic location	
Head/Neck	20 (12.82)
Lower limbs	28 (17.95)
Upper limbs	34 (21.75)
Trunk	8 (5.13)
Multiple	14 (8.97)
No data	52 (33.33)
Evolution period, weeks	
1-15	84 (53.85)
16-30	22 (14.10)
31-45	5 (3.20)
≥45	1 (0.64)
No data	44 (28.20)

3.3. Therapeutic response of children who received treatment at PECET

Of the 156 patients evaluated at PECET, a total of 114 children (73.08%) received treatment at the research center. Forty-two patient

did not received treatment at PECET, so they were not considered for the analysis of therapeutic response.

As first treatment option, the most commonly used therapies were local treatment (approximately 69.30%, 79/114). Twenty-six (26/114) patients received an additional treatment due to therapeutic failure, reactivation or medical improvement: twenty-five children (21.93%, 25/114) required a second treatment option and only one (0.88%, 1/114) received three different therapeutic options (Table 3). During the first therapy cycle, the most effective alternative with the highest cure rate was intralesional meglumine antimoniate, with a cure rate of 43.18 % (19/44). It was also the therapeutic option with the highest percentage of reactivation, at 18.18 % (8/44) (Table 3).

In the second treatment cycle (21.93%, 25/114 patients) the local therapeutic alternatives were also the most commonly used, accounting for 72.00% (18/25). The most frequent alternative was intralesional meglumine antimoniate, with a cure rate of 43.75% (7/16). For the systemic options used at the second cycle of treatment, we found a cure rate 100.00% (3/3) for miltefosine and 75.00% (3/4) for meglumine antimoniate.

For the one patient who required a third therapeutic option, topical amphotericin B was initially used as the first treatment option, but the patient experienced therapeutic failure. Systemic meglumine antimoniate was then administered as second option, but it also resulted in therapeutic failure. Finally, intralesional meglumine antimoniate was applied as his third treatment option. However, the patient discontinued follow-up and we were unable to obtain information regarding the final outcome (Table 3). Given the particularity of the case, the clinical history was analyzed, and it was found that the patient had no prior history of *Leishmania* infection, had 4-month evolution of the lesions, a total of 4 skin lesions, and had positive results from direct examination, culture for *Leishmania* spp., PCR, and typing of *Leishmania panamensis*.

3.4. Safety associated with the use of different therapeutic alternatives for CL

Twenty three patients from the 144 who received treatment, at some point reported an adverse event during treatment period. As for safety, adverse events were reported according to treatment and were discriminated by the route of administration (systemic or local). For systemic treatments, the most predominant adverse events were observed with the use of meglumine antimoniate (8/24 patients): abdominal pain (2/24), arthralgia (2/24) and myalgia (2/24). One patient that reported myalgias also reported hyporexia and another one reported headache and fever associated to treatment. In the case of miltefosine, five of the fourteen treated patients reported an adverse event: nausea (3/14) and vomiting (2/14). There was no information reported about adverse events related to pentamidine.

Table 3. Therapeutic response to different treatment regimen [n (%)].

Therapeutic response	First treatment cycle						Second treatment cycle						Third treatment cycle	
	Systemic treatment (n=35)			Local treatment (n=79)			Systemic treatment (n=7)			Local treatment (n=18)			Local treatment (n=1)	
	Meglumine antimoniate (n=20)	Miltefosine (n=11)	Pentamidine (n=4)	Intralesional meglumine antimoniate (n=44)	Topic Amphotericin B (n=10)	Thermotherapy (n=5)	Research topic (n=20)	Meglumine antimoniate (n=4)	Miltefosine (n=3)	Intralesional meglumine antimoniate (n=16)	Thermotherapy (n=1)	Research topic (n=1)	Intralesional meglumine antimoniate (n=1)	
Cure	8 (40.00)	3 (27.30)	0 (0.00)	19 (43.20)	0 (0.00)	1 (20.00)	5 (26.30)	3 (75.00)	3 (100.00)	7 (43.75)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Clinical im-provement	9 (45.00)	5 (45.50)	1 (1.80)	9 (20.50)	1 (10.00)	0 (0.00)	2 (10.50)	0 (0.00)	0 (0.00)	7 (43.75)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Reactivation	0 (0.00)	0 (0.00)	0 (0.00)	8 (18.18)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Therapeutic failure	1 (5.00)	0 (0.00)	1 (25.00)	1 (2.27)	4 (40.00)	2 (40.00)	5 (25.00)	1 (25.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Follow-up loss	2 (10.00)	3 (27.27)	2 (50.00)	7 (15.91)	5 (50.00)	2 (40.00)	7 (35.00)	0 (0.00)	0 (0.00)	2 (12.50)	1 (100.00)	1 (100.00)	1 (100.00)	1 (100.00)
Drug discontinued due to adverse events	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (5.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)

All these events were of mild intensity and self-resolved.

Regarding the adverse events recorded in children who received local treatments, it was found that the symptoms primarily occurred during drug application. With the application of intralesional meglumine antimoniate, 3/61 patients experienced local pain, 2/61 edema, 1/61 erythema and 1/61 generalized rash. One patient presented a bacterial infection of the wound during posttreatment care in this treatment group. All of these events were of mild intensity.

Ten patients treated with topical amphotericin reported no adverse events. From thermotherapy group (2/6), one patient experienced generalized rash and one reported itching. One patient who received topical treatment in research (1/21), reported edema and erythema together.

The grading of adverse events was based on Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0.

4. Discussion

The results of this study provide the sociodemographic and clinical characterization of 156 minors diagnosed with CL who were treated at PECET over a decade. In addition, it includes information on the therapeutic response and safety of various treatment alternatives administered at the center. Based on our knowledge, this is the first report on the performance of different treatment options with a local route of administration in children.

Leishmaniasis is a health event of interest in our country, because it is particularly prevalent in rural areas, where it primarily affects vulnerable populations. Although the age group most affected by *Leishmania* infection is adults aged 20-29 years, who are considered the working population[8], there is a notable number of CL cases in the pediatric population. This is due to continuous exposure to *Leishmania* spp. from an early age and the lack of a specific immune response against the parasite at that time of life[9].

According to Pan American Health Organization/World Health Organization (PAHO/WHO) 2022 epidemiological report[4], 10% of newly diagnosed cases of CL in the Americas were under 10 years of age. In countries such as Honduras, Panama, Costa Rica, Nicaragua and El Salvador, the incidence of pediatric cases can reach 30% of all reported cases.

As reported in the adult population, most cases were from rural areas (75.6%)[8]. A predominance of infection in men was observed in terms of sex. This finding is of particular interest because, although it may be linked to outdoor activities and fieldwork (behaviors traditionally associated with males in our country) it contrasts with the findings of a study, where exposure to the parasite in children between 6 and 12 years was similar for both sexes. This could be explained by the evening activity of the vector, that had contact with

children in their residences[10].

PECET is a research center recognized by the Colombian Ministry of Science and Technology. The center has research units in the areas of product development and clinical trials and holds Good Clinical Practice (GCP) certification, which allows it to access various treatment options and conduct evaluations of new alternatives and/or regimens. As a result, it was possible to analyze both treatments included in national guidelines and those under investigation.

Regarding efficacy, the limitations of pediatric response to the treatment options available for the management of CL in this population are well known. It has been shown that systemic treatment in children can have low effectiveness and may even be associated with cases of resistance[12], due to increased drug elimination and reduced drug absorption[13]. However, the lack of scientific evidence on the performance of local treatment options based on the clinical characteristics of the patients has restricted their use. Additionally, evidence indicates that lesions in this population are usually located on the face and neck[6,11], which, to date, contraindicates the use of local therapies in many cases, leading to the use of systemic options such as pentavalent antimonials or miltefosine.

In this study, the majority of patients' lesions were located in the upper limbs (21.75%), followed by lesions in the lower limbs (17.95%). This finding aligns with the Venezuelan study by Ortega-Moreno *et al*, which also reported a predominance of lesions in the extremities[14], and contrasts with Castro *et al*, where the head and neck are the predominant anatomical location for lesions in among similar population[6].

The clinical and epidemiological characterization of patients, as well as understanding the performance of different systemic and local therapeutic options, are fundamental for determining the best treatment approach and guiding recommendations for this particular population. This underscores the need for studies like the present one, which clarify the disease's behavior in specific population, such as the pediatric population, and contribute to the enrichment of scientific evidence, providing guidance to healthcare professionals and authorities in disease management.

In terms of safety, the most common adverse events reported in our population were abdominal pain, myalgias, and arthralgias associated with the use of systemic meglumine antimoniate, as well as nausea and vomiting related to the use of miltefosine. These symptoms are consistent with a study conducted on minors in Latin America[14,15]; additionally, the lower proportion of adverse events associated with systemic treatments in children, compared to those reported in adults, is also confirmed[16]. For local treatments, adverse events were primarily related to discomfort, including pain, edema, erythema and skin rash at the site of application, all classified as mild intensity. These findings align with what has been reported for local treatments in other populations[8,17]. It is important to note that

this study lacks the rigor of a clinical trial; therefore, the recording of adverse events was not exhaustive.

Considering the results obtained in this study and in similar studies, where the efficacy of miltefosine is comparable to systemic meglumine antimoniate[16], and given its favorable safety profile and non-invasive route of administration, we consider the use of miltefosine as a favorable therapeutic option for minors[7]. However, the use of topical therapies such as intralesional meglumine antimoniate and thermotherapy, should not be ruled out, as these alternatives demonstrated acceptable percentages of cure and clinical improvement in the study population. Local treatment options have excellent safety profiles, along with the advantage of being non-invasive[18]. Prior to 2022, intralesional meglumine antimoniate was used in a non-standardized way regarding its administration dosage, so it is possible that the results obtained prior to this date in the patients in this study reflect this variability. With standardized dosage and administration, this drug could be a valuable therapeutic option for the pediatric population.

Due to the advantages in terms of safety and adherence, recommendations for the use of local treatments, such as thermotherapy and intralesional meglumine antimoniate, have increased as the first treatment option for CL, particularly in patients with few lesions, those that are small (<3 cm) and those not located on the face or joints[11]. Based on the results of the clinical characterization of the population's infection and their response to different treatments, the recommendation to use local therapeutic alternatives as the first-line treatment could be extended.

We are aware of some limitations identified during the study should consider when analyzing the results and conclusions. These include: 1. The research center is a reference facility located in the northwestern region of Colombia, which led us to consider two factors: first, that most patients come from nearby municipalities and departments, excluding the characteristics of the populations from other parts of the country (selection bias), and second, as a specialized center, many of the patients attended are those with clinical conditions that are difficult to manage (referral bias). 2. The loss of patient follow-up, particularly in those treated with topical therapies, limited the information available regarding the performance of the different treatment options (information bias).

In conclusion, the need for prospective studies to evaluate the efficacy and safety of different therapeutic options in the pediatric population is evident in order to generate evidence-based recommendations and management protocols. Nevertheless, the results regarding therapeutic response and safety profiles shown by miltefosine, intralesional antimoniate and thermotherapy, observed in children with CL treated at the research center, suggest that these alternatives are safe, effective, and affordable options for managing this condition in this population.

Conflicts of interest statement

All authors declare there is no conflict of interest.

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Authors' contributions

LLC and CB participated in the conceptualization; LLC and SRE participated in the methodology; LLC, SRE and JQP participated in the validation; LLC and SRE participated in the formal analysis; SRE participated in the data curation; SRE, LLC, and JQP participated in the writing—original draft preparation; SRE, LLC, JQP and CB participated in the writing—review and editing, and LLC participated in the supervision. All authors have read and agreed to the published version of the manuscript.

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