Chapter

Epidemiology of Visceral Leishmaniasis in India

Rajan R. Patil and Prabir K. Chatterjee

Abstract

Kala-azar is a leading parasitic infection of great epidemic and mortality potential. More than 90% of Incident cases brought to notice of WHO in 2019 were mainly reported from 10 countries. Four endemic states in India namely Bihar, Jharkhand, Uttar Pradesh and Jharkhand have high disease burden of Kalazar. All 4 endemic states have to mandatorily notify cases to the National Vector Borne Disease Control Programme (NVBDCP) every month, even if there are zero cases. In recent years of Kala-azar cases, India have witnessed reduction of 97% largely due to the introduction of single-dose AmBisome –in India has been the game changer. There are three forms of leishmaniasis seen in India Kala-azar, they are Visceral Leishmaniasis, Post Kalazar Dermal Leishmaniasis (PKDL) and Cutaneous leishmaniasis. PKDL patients harbor the parasite and may be the source of new infection to the vector even 20 years later. Poverty enhances the risk for Kala-azar. Poor housing and domestic sanitary conditions are good breeding ground for sandfly which is the vector for Visceral Leishmaniasis, as well as resting sites and their ease of sandfly contact with humans. Kala-azar is a climate-sensitive disease as any change in temperature and humidity influences vector breeding.

Keywords: Kalazar, epidemiology, leishmaniasis, tribal population, India

1. Introduction

Kalazar is the widely used term for Visceral leishmaniasis (VL) in India. As per WHO Global Health Observatory, which is basically distribution maps of VL cases using the DHIS2 platform and has an interactive dashboard [1], VL is endemic in 78 countries. India, East Africa, and Brazil are the countries where most cases occur. Worldwide, about 50,000 to 90,000 new KA cases occur every year, however, only 25–45% are reported to WHO [2].

Kala-azar is a leading parasitic infection of great epidemic and mortality potential. More than 90% of incident cases that are brought to the notice of WHO in 2019 were mainly reported from 10 countries: India, Eiteria, Iraq, Somalia, Brazil, Ethiopia, Kenya, South Sudan, Sudan and Nepal. India's share of global burden of Kala-azar in 2020 has been 18%. Kala-azar remains a significant public health issue in India with 54 districts scattered in four states — Bihar (33 out of 38 districts), Jharkhand (4 out of 24 districts), Uttar Pradesh (6 out of 75 districts) and West Bengal (11 out of 23

districts). Stratified analysis showed that there are 633 blocks spread over four states which are endemic. Sporadic cases are also detected in states like Gujarat, Assam, Himachal Pradesh Haryana Tamil Nadu, Puducherry, Madhya Pradesh, Kerala, Sikkim, Uttaranchal and Jammu & Kashmir [3].

As per the instructions received from National Vector Borne Disease Control Programme (NVBDCP), All 4 states endemic to Kala-azar, namely Bihar, Jharkhand, West Bengal and Uttar Pradesh, have to mandatorily notify cases of the NVBDCP every month, even if there are zero cases. The spot map of Indian subcontinent (**Figure 1**) shows the distribution of various species of Leishmaniasis prevalent in India and its neighboring countries. Within India, Kalazar is clustering in eastern India as per data collected in last 2015 to 2019 [4].

Leishmania donovani is the pathogenic organism for Kalazar, and *Phlebotomus argentipes* is the main vector, particularly in India, commonly called as sand fly. Animal carriers are not known in India, though in a few countries, animal carriers [5] do exist in Europe e.g., foxes, and in China dogs are known to carry the infection. Disease spread of Kalazar is highly localized: over 3/4th of inferred infectors are seen to be at a mean distance <300 m to their respective secondary VL cases.

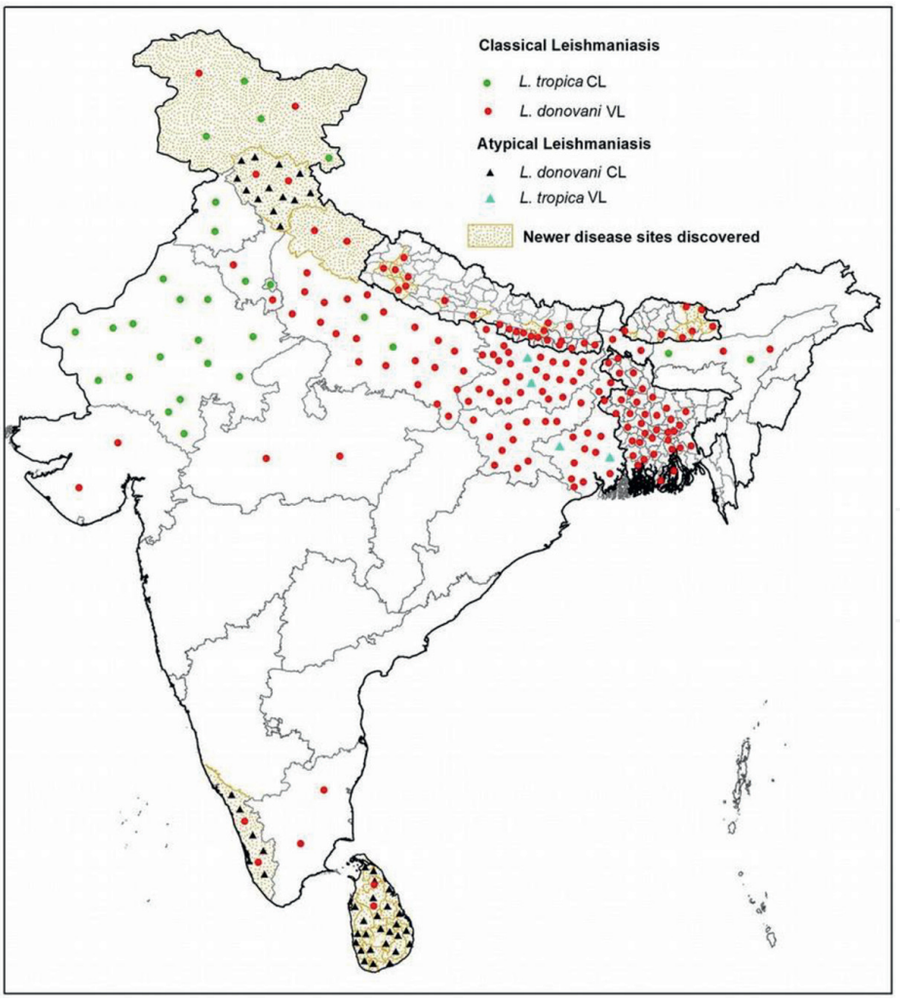

Figure 1.
Distribution of Kala azar in Indian subcontinent. Clustering of Kalazar cases in India and neighboring countries.

After many years (since 1992) of accelerated Kalazar elimination programme implementation, the cases of Kalazar cases in India have witnessed a reduction by 97%, while the reported deaths have fallen from 1419 in 1992 to 58 in 2018, and only 37 deaths were reported in 2020, formally [6].

Kalazar elimination as a public health problem is defined as achieving an annual incidence of less than 1 case per 10,000 population at the district level in Nepal and at the subdistrict level in Bangladesh and India.

National Kalaazar Elimination Programme NKEP, now integrated into National Vector Borne Disease Control Programme (NVBDCP) has set an ambitious goal of zero KA transmission by 2030. This goal will be attained through early diagnosis and prompt treatment, integrated vector management, operational research, effective disease surveillance, supervision, monitoring and evaluation and social/community mobilization and partnerships [7].

2. Kalaazar (visceral leishmaniasis)

Kalazar in its severe form is associated with high mortality in the absence of prompt diagnosis and treatment. Kalazar is prevalent in all the countries **Figure 2** in Indian subcontinent [4]. After Malaria, Kalazar comes second in ranking for causing maximum number of deaths by a parasitic disease. It is reported that 20,000

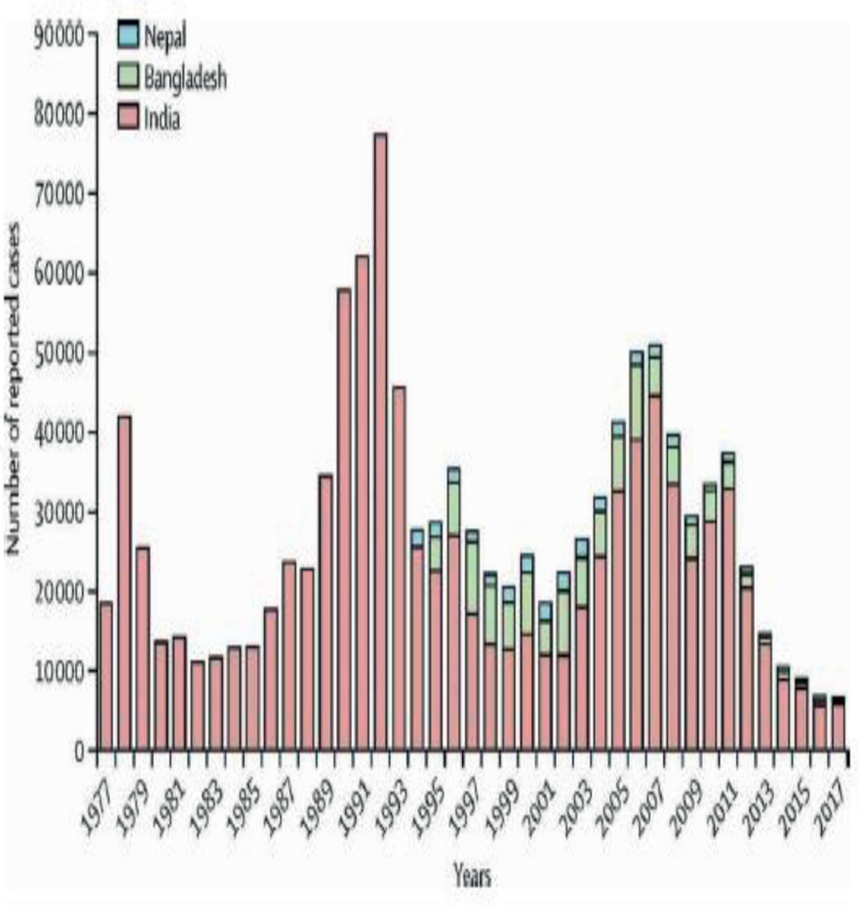

Figure 2.
Depiction of reported comparative reporting of Kala-azar cases in India, Nepal and Bangladesh from 1977 to 2017 [8].

Signs	Diagnosis
Loss of weight	Low hemoglobin
Wasting	Low white blood cell
Severe pallor	Low total count
Enlarged spleen	Low platelet count
	Bone marrow reveals Leishman-donovani (LD) bodies
	Molecular (PCR) Immunological (ELISA, rapid tests) assays. Other tests include rK39 strip test

Table 1.
Signs and diagnosis of Kalazar.

to 30,000 deaths occur worldwide due to Kalazar. The term Kalazar is derived from the word 'kala' which means black referring to black discoloration of skin in kalazar affected person. Since there is great similarity between the symptomatology of Kalazar and Malaria, the propensity to misdiagnose the disease is common. Misdiagnosis is perilous to the patient as the case fatality rate in Kalazar cases is 100% in the absence of proper treatment. In severe Kalazar, the death of the patient is not due to pathogen (L D bodies) but instead, due to opportunistic infection resulting from immune-compromised status due to Kalazar disease. The death by Kalazar is often due to secondary infections such as Dysentery, Pneumonia and Tuberculosis. which are highly prevalent in the communities where Kalazar is rampant [9, 10].

Symptoms of Kalazar are fever with chills. Generally, fever occurs twice a day. If not diagnosed and treated, the fever continues, though it is not so high after the initial days. Loss of appetite and severe weakness are other symptoms (**Table 1**).

3. Post-kala-azar dermal leishmaniasis

Post Kalazar dermal Leishmaniasis is a complication of Kala-azar, and is mainly seen in India, South-East Asia, and East Africa. It is manifested by discolored (hypopigmented) flat skin (macular) rash, combined with some slightly elevated (maculopapular) or elevated (nodular) rash. It is manifested in Kalazar patients who are cured of the VL. Manifestation of Post-kalazar dermal leishmaniasis (PKDL) usually occurs in the period of six months to one or more years after treatment and cure of Kala-azar, at the same time it may occur earlier or even along with Kala-azar. PKDL heals spontaneously in most cases in Africa but rarely in patients in India [11, 12]. PKDL patients harbor the parasite and may be the source of new infection in susceptible children even 20 years later.

In 6 districts of Bihar peak PKDL was in 2018 and in 2 districts it was in 2017. Recent papers suggest that the 2 districts achieved control around 2015 and elimination is likely between 2021 and 2023. In other districts it will not happen before 2022 given current spray rates (less than 50% in Kishanganj, between 60 and 70% in Gopalganj and Patna), endemicity (>2) and delays in treatment (60 days). PKDL was increasing in Jharkhand. There were 1800 reported cases of PKDL in India in 2020: 1034 were in Bihar, 502 in Jharkhand, 108 in UP and 156 in West Bengal. (NVBDCP, Ministry of Health, Govt of India.)

4. Cutaneous Leishmaniasis

Cutaneous Leishmaniasis is Less prevalent in India- sporadic cases are found in western India. Cutaneous manifestations are characterized by skin lesions mostly ulcers especially on exposed parts such as face, neck, and extremities. Skin lesions are the major reason for disability and stigma. As per the reported cases, 95% of cutaneous leishmaniasis worldwide comes from American continent, the Mediterranean region. There is gross under reporting of cutaneous leishmaniasis, it is understood that the actual number of cases may be in the range of 600,000 to 1,000,000, however only 200,000 cases are reported to WHO.

In the Indian region, Cutaneous Leishmaniasis is a highly localized public health problem in western India, restricted to one state of Rajasthan, especially in the Thar desert of Bikaner district. It is located at the center of Thar desert. The Bikaner city is surrounded by stone walls. Bikaner being a desert city expectedly the weather will be hot and dry with very little rainfall [13, 14].

Less common in India- mostly found in western India. CL cases were reported in 4 in Jammu, 2 in Punjab, 1 in Haryana, 1 in Delhi, 16 in Rajasthan, 2 in UP, 2 in Assam/Atypical CL 13 in Himachal, 2 in W Bengal, 5 in Kerala, 1 in Andhra, 2 in Maharashtra, 2 in Gujarat. (NVBDCP, Ministry of Health, Govt of India.)

5. Kala-azar-HIV co-infection

The chance of developing visceral Leishmaniasis clinical manifestation of disease accompanied by high relapse and death rates is very high in Kalazar-HIV coinfected cases due to Immuno- compromised status. Prompt treatment with antiviral treatment decreases the chance of disease development, keeping in check the relapses and enhancing the survival rates [15].

As of 2021, leishmania-HIV co-infection has been reported in 45 countries. Brazil, Ethiopia, and the state of Bihar in India have reported high Leishmania-HIV co-infection rates [16].

Due to the low immunity in Kalazar patients, many other co-infections, such as Tuberculosis and Dysentery, are commonly seen. Malaria and TB co-exist in Jharkhand.

Bleeding from Gums occurs due to low platelet count. Also seen is Noma (a Cancrum oris like growth) a known complication VL-HIV co-infection cases were 141 in 2018 and 91 in 2019 in Bihar. They were 7 in 2018 in Jharkhand and 2 in 2019. (NVBDCP, Ministry of Health, Govt of India.)

6. Treatment

Treatment of Kalazar is not simple, the drug administration should necessarily be done by trained health personnel since most of the anti-leishmanials are injectable drugs. All the Kalazar affected cases are required to comply with the drug regimen and take complete treatment [16].

Early diagnosis and prompt treatment of Kalazar result in decline in the prevalence of the Kalazar disease and hence reduction in the resultant disability and death. Epidemiologically, it helps in interrupting the chain of transmission subsequently reduction in disease burden in the community. Although anti-leishmanial drugs are

costly, however highly subsidized procumbent by WHO has brought down the cost of medicine. Affordable medicines have helped improve access to essential medicine making in public health institutions. Good part is anti-leishmanials that are absolutely free to all the Kalazar patients [17, 18].

Liposomal Amphotericin-B (AmBisome) is the safest and effective injection. Other medicines include Sodium Stibonate (Antimony) Gluconate or SSG injections. Oral medicine Miltefosine, and Paramomycin (Injection)- which appear to be less effective.

6.1 Dosing

AmBisome is given as a Single dose in India and as 6/7 Doses in other countries (4 mg/kg/body wt.). SSG is given as 20 mg/kg body weight once a day for 30 days.

Miltefosine is given as 100 mg/day. Metclopramide – 5 mg/day is given along with Miltefosine.

Although single-dose AmBisome treatment is available in all endemic areas and satisfactory cure and relapse rates are reported (>95%). Significant delays between onset of symptoms and treatment were noted in Bihar and Jharkhand, due to the lack of diagnostic capacity at facility and case management.

7. Major risk factors

Socioeconomic conditions: Poverty enhances the risk for Kala-azar. Poor housing and domestic sanitary conditions are good breeding ground for sandfly which is the vector for Visceral Leishmaniasis, as well as resting sites and their ease of sandfly contact with humans.. The mud plastered on a bamboo framework with cracks in the walls of houses is a typical breeding place. Lack of sunlight (due to there being no windows) is another feature as cool, dark spaces attract sandflies. Houses with crowding attract sandflies as these provide a good source of blood meals. Human behavior, such as sleeping outside or on the ground, may increase risk. Sandflies are zoophilic. So, keeping cattle inside the house and sleeping close by increases the chance of human beings getting Kalazar [19].

Malnutrition: Diets lacking in protein-energy, iron, vitamin A and zinc increase the risk that an infection will progress to a full-blown disease.

Population migration and movements of non-immune population in areas with active infection circulation are ideal conditions for epidemics of cutaneous as well as Kalazar.

8. Environmental changes

Kalazar is climate-sensitive as it affects the epidemiology in several ways:

- Vectors and reservoir get influenced by temperature changes, humidity, and rainfall by geospatial distribution which in turn is determinant of their survival and population size [20].

- Minor fluctuations in temperature could have a significant effect on the life cycle of *Leishmania* promastigotes in sandflies, facilitating transmission of the parasite in geographical places not previously endemic for the disease.

- Disasters like flood, drought and famine lead to massive human migration of population to newer areas that may or may not have Kalazar which may initiate fresh Kalazar transmission [21].

India has significantly improved Kalazar control programme. In endemic villages that have reported cases of Kala-azar over the past 3 years, 2 rounds of indoor residual spraying are being applied. Development of resistance in vectors has been the major challenge in efforts towards Kalazar elimination especially to pesticides such as DDT has led to the introduction of synthetic parathyroid for indoor residual spray in 2015 [22].

9. Public health intervention for Kalazar elimination

A series of public health measures have sustained the Indian Kala-azar elimination drive. These include:

- Capacity building of human resources and financial commitment;
- Case-based surveillance and micro-stratification in high-risk areas;
- For monitoring programme and initiate prompt action a new platform is introduced electronic health records to facilitate, KA Management Information System (KAMIS) [23];
- Introduction of new, single-dose liposomal amphotericin B treatment;
- In Kalazar-endemic areas, construction of concrete houses;
- Alphacypermethrin for Indoor Residual Spray (IRS) (replacement of DDT by 5%) since 2016;
- Introduction of superior hand compression pumps fitted with control flow valves for IRS (2015); Regular monitoring and evaluation of programmes by technical advisory groups, and collaboration with an effective network of partners.

The KA Management Information System (KAMIS) for NKEP which is essentially a web-based online platform has been in use since 2014. KAMIS holds electronic records of all KA and PKDL cases since 2013, along with data on drugs and diagnostics, IRS monitoring and vector surveillance. Data are entered in real-time at the implementation level by trained data operators.

To ensure prompt diagnosis and effective treatment, financial incentives are provided to community health workers, and wage losses have been compensated for KA and PKDL cases, with a good referral system with free of cost ambulance service. All Kalazar and PKDL patients are beneficiaries of the national health insurance scheme called Ayushman Bharat and avail absolutely free of cost health services including admission.

9.1 The reasons

Despite wonderful progress, last-mile challenges remain to eliminate Kala-azar. The reasons are varied ranging from factors such as difficult geographical terrain,

indigenous populations, poor socio-economic conditions poor health-seeking behavior conditions, inadequate housing, and difficulties facing the implementation of the Kala-azar programme [24, 25].

With a progressive decline in cases, it is very important to maintain strong surveillance – this is now being integrated with those of other health surveillance programmes. Intensified governmental initiatives and political will has kept Kalazar elimination on high action alert.

10. Challenges in Kalazar elimination

There are several challenges that are encountered in attaining Kalazar elimination in India broadly they can be categorized as public health management, Biological factors & adverse impact pandemic on the operational aspect of Kalazar [26].

10.1 Challenges in surveillance and case management

Even though KA clusters are known, early diagnosis remains a challenge. KA symptoms are non-descriptive and nonspecific, ruling out other prevalent febrile diseases is the best way of finding KA-suspected cases. The first point of contact in endemic rural areas for Kalazar with fever is over-the-counter consultation with pharmacist or rural health practitioner, which is responsible for delay in treatment-seeking by 35–39 days at public health institutions. However, treatment-seeking delay at public health institutions ranged from 35 days in Bihar, however, it was lower in Jharkhand, 30 days. In lower endemic states the delay was much higher, 45 days in up and 50 days in West Bengal.

There are great hindrances in KA Surveillance when villages that have not previously reported KA begin to report KA cases from such villages, although they are located within known endemic blocks and districts. The number of such villages is declining each year, from 1001 in 2018 to 627 in 2019 and 87 in 2020.

10.2 KA elimination programme

Two significant challenges in KA–HIV coinfection and PKDL which are being obstacle to KA elimination. The percentage of KA cases with HIV has remained stable at 2–5%, while surveillance for PKDL has been fluctuating, with no known baseline of the disease burden.

Little is known about the outcomes of treatment of KA-HIV coinfected and PKDL cases. Certainly, the quality of diagnosis has improved significantly, however, identification of relapsed cases is being done in a few tertiary care health facilities [27].

10.3 Indoor residual spraying

According to national protocol, challenges in IRS as per guidelines, 2 rounds of IRS are conducted every year for sand fly control; however, the timing of IRS and the duration of spray rounds are affected by local contexts, IRS activity is affected by crop harvesting, elections, rains, migrations for work, all of which lead to delay in spraying activities or incomplete coverage [28].

As the spray pumps used in the programme are imported, obtaining spare parts (controlled flow valves, nozzle tips, lead gaskets, filter strainer) has been a challenge.

10.4 Impact of Covid-19 on Kalazar control programme

The COVID-19 pandemic has adversely impacted KA elimination programme since early 2020; despite the pandemic essential vector control and case management activities have been continued. The impact of COVID-19 on NKEP is yet to be assessed. With the shrinking geographical distribution of KA cases, having a strong surveillance system becomes paramount, in an effort to integrate KA case searches with those of other health programmes in a few KA-endemic states. Access to health care services especially for KA-HIV co-infected cases is challenge as they have to travel 160–240 km for treatment at a specialized tertiary hospital, Institutions of excellence are being set up to improve access health care to specialized care for complex KA cases and to build the trained health workers for case management [29].

Inter-sectoral Coordination among health and non-health departments and clarity in roles and responsibilities among all sectors, community mobilization will be key to sustaining the gains in the post-elimination phase [30].

11. Conclusions

Strengthening of Kalazar surveillance is key component of Kalazar elimination programme through strategic human resource planning in the health system. In the last leg of Kalazar elimination efforts have to be in mission mode. Both types of management styles are bottom-up as well as top to bottom. On paper, India has one of the finest national guidelines for the elimination of Kalazar, however, translating it to practical ground application with required resource mobilization would be primary pre-requisite. The use of quality epidemiological data is necessary to make an evidenced-based decision. Keeping with the spirit of national health policy there is a need for avoiding temptation of health systems to run Kalazar control programme as a vertical program, instead of integration with primary health care. Vector control against sand flies needs to take the holistic approach of integrated vector control methods.

Author details

Rajan R. Patil[1*] and Prabir K. Chatterjee[2]

1 KLE University, Belagavi, India

2 Amder Hospital, Bankura, India

*Address all correspondence to: rajanpatil@yahoo.com

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