Brief summary

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Detection of asymptomatic *Leishmania* infection in blood donors at two blood banks in Ethiopia

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Key Messages

- Visceral leishmaniasis (VL) is a disease caused by *Leishmania* parasites, and fatal if left untreated.
- *Leishmania* parasites have been found in blood products of healthy donors in some VL endemic areas. Cases of VL transmitted through blood transfusion have been reported, particularly in immunocompromised recipients.
- Despite Ethiopia being one of the highest reporting countries for VL worldwide, this potential problem has never been investigated.
- We tested blood samples from presumed healthy blood donors presenting at two blood bank sites (Metema, high number of cases; and Gondar, low number of cases) in northwest Ethiopia for *Leishmania infection*
- Asymptomatic *Leishmania* infection was found in high proportion of blood donors, up to 15% in the VL endemic site (Metema).
- Future research should be directed at better defining the risk of acquiring Leishmaniasis disease in blood recipients, especially in immunosuppressed ones.

What is the problem and why is it important?

Visceral leishmaniasis (VL) is a vector-borne disease caused by *Leishmania* parasites. Most people remain asymptomatic upon infection. Active disease presents with fever, enlarged organs and affected blood cell lines, and if left untreated, it is fatal. About 20% of VL patients in northwest Ethiopia are co-infected with HIV, which is linked to a grim prognosis.

Notably, *Leishmania* parasites have been discovered in the blood of seemingly healthy donors in VL endemic regions across the globe. Concerning is that cases of VL via blood transfusion have been reported as well, particularly in immunocompromised recipients.

Despite the fact that East-Africa reports the highest number of VL cases worldwide, neither blood donors nor blood products are screened for *Leishmania.* This is because there is no evidence of concern. Thus, we investigated the prevalence of asymptomatic *Leishmania* infection among healthy blood donors at two blood bank sites in northwest Ethiopia.

How did we measure it?

We collected blood samples from a total of 426 presumed healthy blood donors from Metema (VL-endemic site) and Gondar (VL non-/low-endemic site). The following tests were done:

- Serological tests: rK-39 RDT, rK39 ELISA and Direct Agglutination Test (DAT) → exposure to parasite (previous or current)
- Molecular test: PCR→ presence DNA of the parasite

Asymptomatic *Leishmania* infection was defined if at least one of the tests was positive in a presumed healthy donor. Factors associated with asymptomatic *Leishmania* infection were determined.

What did we find?

- The prevalence of asymptomatic infection was 15.0% in Metema (VL endemic) and 4.2% in Gondar (VL low-/non-endemic)
- The most common positive tests were rK39 ELISA (n = 23; 5%) followed by rK39 RDT (n = 11; 3%) and PCR (n = 11; 3%). Only 2 patients with positive DAT from Metema
- The tests we have done has limitations as there is no gold standard to diagnose asymptomatic infection world wide and there is a possibility of a few false positives. PCR is accurate but showed low parasite load.
- Except for the blood bank site, none of the sociodemographic data was found associated with a higher prevalence

Implications

- There is an indication of *Leishmania* infection in the blood products of presumed healthy blood donors, especially in high endemic regions, which could be a potential threat for (immunocompromised) recipients.
- Results should be interpreted with care because of test limitations (few potential false positives), the lack of a gold standard to define asymptomatic carriers and because blood parasitemia was low.
- Actual potential of transmission should be investigated in future studies to decide whether blood products of donors should be systematically screened in VL endemic areas.