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Abstract

Background: Leishmaniasis is a protozoan parasitic disease transmitted by sand fly bites. Visceral leishmaniasis (VL) is a chronic intracellular infection which, when symptomatic, can be fatal without therapy. Subclinical or latent VL may occur in a majority of those infected with lifelong risk of activation when immunosuppressed. Symptomatic VL has been described in Soldiers deployed to Operation Iraqi Freedom (OIF). We report the prevalence and risk characteristics of latent VL infection in OIF Soldiers.

Methods: Healthy Soldiers deployed during summer months (2002-2011) to VL endemic areas of Iraq were recruited from Fort Bliss, Texas. Responses to a risk factor survey and blood samples were obtained. Leishmaniasis research diagnostics were performed on serum and white blood cells to include ELISA, rK39 immunochromatography, qPCR and interferon-gamma release assay (IGRA) assays. Analyses included descriptive statistics and logistic regression. Fisher's Exact test and logistic regression were used for group comparisons.

Results: Out of 88 subjects enrolled, 70 (88%) were male with median age 39 years and deployment duration of 5 years. The prevalence of latent VL was 10.2% (C.I. 4.8%-15.5%) with 7 ELISA-positive and 2 ELISA-negative positive. Travel to Ninewa governate correlated with VL, p<0.05. No significant differences were noted in occupation, personal protective measures, deployment timeframe, or sleeping conditions between VL positive and negative individuals. In U.S. Armed Forces: 25 cases of visceral leishmaniasis, 1186 cases of cutaneous leishmaniasis were reported from Iraq Ministry of Health. Approximately 10.2% of tested subjects were positive for LVL.

Materials and Methods

- Study Design and Selection: A cross-sectional study with 4 blood samples and 1 risk factor survey assessing for latent VL risk exposure. The study was conducted from October 2002 to January 2011 in Fort Bliss, El Paso, TX. This is a part of a multi-site cohort study that also included the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Uniformed Services University of the Health Sciences (USUHS), Texas Tech University Health Sciences Center El Paso, and ASMAC, with diagnostic studies performed at UHMSI, with studies of military personnel deployed to the Middle East.

- Leishmania: VL infection was defined using standard of care KOH immunochromatographic testing (Kol Pak Detect™), ELISA, qPCR, and Inferon Gamma Release Assay (IGRA). Initial lab processing was conducted at WBAMC, then diagnostic studies were performed at USUHS. Chagas serology on ELISA positive samples was done to rule out cross reactivity with Trypanosoma cruzi infection.

- Statistical Analysis: Univariate analysis was used to determine predictors for the above four test results. Univariate models were applied to determine covariates and possible confounders. All statistical analysis was conducted using SPSS software.

- Results: 88 subjects were recruited. Exclusion of patients with a history of malignancy, transplant, chemotherapy, or prior leishmaniasis infection. No cross reactivity with Trypanosoma cruzi infection.

Discussion and Implications

- Approximately 10.2% tested positive for LVL. Ft. Bliss cohort is part of a larger cohort in a multi-site study in the U.S. Armed Forces.

- Previous rate at 1.2% of overt VL in U.S. Armed Forces from 2001-2016.

- Potentially large number of undiagnosed deployed military members.

- No evidence for association of VL infection with:
  - Standard demographic or occupational characteristics
  - Year of deployment
  - Vaccine or preventative countermeasures
  - Animal encounters
  - Current reported symptoms or evidence of illness

- Deployment to Ninewa governate, (includes Mosul) conferred increased risk of Leishmaniasis infection.
  - Possible reasons: geographic factors, differences in Soldier and/or vector activity differences in methodology/underreporting
  - LVL geographic risk may have been differently distributed compared to initial reports from Iraq Ministry of Health

- Study Limitations
  - Low sample size
  - Experimental assays with performance parameters being evaluated
  - Potential recall bias
  - Multiple deployments and potential travel to Leishmania-endemic areas not related to deployment

- Higher risk of VL reactivation in infected if ever immunosuppressed
  - Possible need for testing prior to start of therapy and/or vigilant monitoring?

- Additional prospective studies planned:
  - Evaluate burden of LVL in currently deployed Soldiers
  - Longitudinal assessment of risks and clinical consequences of VL reactivation

References

2. Bonds TM, Rand Corporation. 2010

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