Reply to Monge-Maillo et al

Monge-Maillo et al [1] raise key issues with respect to New World cutaneous leishmaniasis (CL). One issue is, as stated, that the use of local versus systemic therapy has to address the possibility that local therapy could be associated with a higher risk of later mucosal leishmaniasis (ML). We agree that the risk of ML is an important factor in evaluating local therapy, although we quantitate that risk differently. Monge-Maillo et al give the risk of ML as 16%–37%; however, these numbers come from a review [2] that focused on 1993 primary reports by David and Dimier-David, one of which contains the summary statement that “the true frequency of mucous involvement in Bolivia may be somewhere between 5% and 20%” [3].

A 2012 publication reports that ML incidence between 2001 and 2006 in Bolivia was 14.5% but was decreasing over that time period such that incidence in 2006 was approximately 2.5% [4]. We would say that there is a real risk of ML following CL in Bolivia and in South America generally; however, the risk is hard to quantitate and, at present, may be 2.5%–5% in Bolivia.

Also, it is hard to determine whether local therapies are associated with a higher risk of ML than are systemic therapies. We mentioned that “Factors favoring systemic therapy [include] theoretical elimination of subclinical disseminated parasites” [5], but this is theory and we are not aware of real evidence for or against. As Monge-Maillo et al [1] and Blum et al [2] suggest, long-term follow-up of CL patients to assess ML incidence is needed. This will, however, be a difficult study to perform. The mean time to develop ML from CL may be 2 years [6], and it is likely that the sample size would have to differentiate a 2.5%–5% incidence in the topical group from a hypothesized lower incidence in a systemic group.

Another fundamental CL issue that Monge-Maillo et al bring up is treatment of any type versus no treatment. Although, in the end, the cure rate for our placebo group was low, the cure rate for the cryotherapy group was essentially the same and placebo patients were spared the side effects of the topical treatment. Placebo subjects are also spared what can be a considerable commitment of time to receive therapy. Placebo or no treatment will have low efficacy compared with approved therapies in addition to low toxicity and high convenience. We made sure that potential study subjects were aware of these differences in the consent form.

For New World CL, a sizeable number of patients fail initial management of any type, and rescue therapy for such patients is needed. In our trial, all patients who failed were administered standard systemic pentavalent antimony at the time of failure.
Note

Potential conflicts of interest. Both authors: No reported conflicts.
Both authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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