C1444 CLINICAL EFFICACY AND TOLERANCE OF MILTEFORAN® IN THE TREATMENT OF CANINE VISCERAL LEISHMANIASIS IN NATURALLY INFECTED DOGS WITH L. INFANTUM (SYN CHAGASIA).


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1 Background

In 2007, miltefosine (MIL) was registered in Europe under the brand name of Milteforan® (Virbac, France) for the control of dogs with canine leishmaniasis. More recently, Milteforan® has been registered for its use in Brazil. The aim of this study was to assess the efficacy and tolerance profiles of Milteforan® in dogs with natural Visceral Leishmaniasis (VL) under controlled conditions, by analysing clinical and infective progress, and measuring haematological and biochemical parameters in dogs under treatment.

2 Methods

Dogs naturally infected with L. infantum, and diagnosed as suffering from VL were included and housed in a kennel. All the dogs received the drug orally at the standard dose of 2mg/kg bw once a day for 28 days. During the 12-week follow-up, efficacy was assessed through the reduction of the Clinical Score (CS) and reduction in the parasite load measured by qPCR (at W0, W6, W12) in lymph nodes, bone marrow aspirates, and skin biopsies. Safety was assessed by evaluating the kidney function (BUN, Creatinine), liver function (AST, ALT, GGT), haemogram, total proteins, albumin, and albumin-globulin ratio.

3 Results

36 dogs were included (19 males and 17 females; various breeds; aged 2-5 years). Medical examination, weighing and blood sampling were performed before starting therapy (W0), and then every 14 days for the all duration of the trial (W: 2, 4, 6, 8, 10, 12). For each dog, a CS was established at each time. Over the follow-up period, the dogs showed a weight gain, and a statistically significant decrease of CS (p<0.001). In the animals showing a reduction in the CS (as early as W2 for some of them, or W4 for most of them), the average percent of reduction was 70% (44-100%). A correlation was observed between clinical improvement and parasite reduction in BM, LN aspirates, and in skin biopsies. There was a statistically significant increase in the number of dogs that became negative over time. There was no significant change in kidney parameters (within normal ranges), liver function (normal ranges), or proteinogram during the all observation period.

4 Conclusions

This study demonstrated a significant clinical improvement of the treated dogs, and a strong correlation between clinical improvement and reduction of parasite load (leishmanicidal activity of the drug). In parallel, Milteforan® was well tolerated.