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ORIGINAL RESEARCH

Owners' experiences of administering meglumine antimoniate injections to dogs with leishmaniosis: An online questionnaire study

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Abstract

Background: This study examined the experiences of owners of dogs with leishmaniosis who treated their dogs with daily subcutaneous meglumine antimoniate injections. The owners' perceived ease of administering the injections, the occurrence of problems and the effects on the owners and on the dog–owner bond were evaluated.

Methods: Dogs prescribed meglumine antimoniate as a treatment for leishmaniosis were identified using the database of the veterinary pharmacy of the Faculty of Veterinary Medicine, Utrecht University. An online questionnaire was sent to the owners of these dogs to evaluate the perceived ease of administering the injections, the occurrence of problems and the effects on the owner and the dog-owner bond.

Results: Responses were received from 64 dog owners. Most respondents (78%) reported that administering the injections was not difficult. Pain or the development of nodules at the injection site was reported in 50% and 40% of the dogs, respectively. Polyuria was reported in 44% of the dogs. Some owners reported that administering the injections had a negative impact on their psychological wellbeing (20%), and some would have liked more veterinary support (11%).

Limitations: Some questions were answered by a limited number of people, and their responses may not be representative.

Conclusion: Dog owners remain highly motivated to persevere with meglumine antimoniate treatment and are willing to administer the injections themselves. The availability of active support when needed during the therapy cycle may further improve their acceptance of and confidence in giving the injections.

INTRODUCTION

Canine leishmaniosis is a vector-borne disease transmitted by a phlebotomine sandfly.[1–3] As the sandfly is not endemic in the Netherlands, canine leishmaniosis is mainly diagnosed in dogs imported from endemic regions, particularly from the Mediterranean region. Because the number of dogs imported from endemic regions is increasing in the Netherlands, Dutch veterinarians are increasingly confronted with dogs with clinical leishmaniosis.

Because canine leishmaniosis is a chronic disease, repeated therapy cycles or changes in medication may be needed upon flare-up of clinical signs. Meglumine antimoniate is currently recognised as the mainstay of treatment.[1] Meglumine antimoniate (Glucantime, Mérial) is registered in France as an antileishmanial drug and, as such, can be used according to the cascade agreement in the Netherlands.[4] Other frequently used medications in Europe are allopurinol and miltefosine.[1,3,5,6]

The preferred route of administration of meglumine antimoniate is by subcutaneous injections, as bioavailability upon oral intake is low, and intramuscular injections are reported to lead to more severe injection site reactions.[7] Intravenous injection is associated with maximum bioavailability but makes treatment costly and cumbersome because it requires the daily intervention of a veterinarian. The percentage of remission in dogs with leishmaniosis treated with intravenous and subcutaneous meglumine antimoniate injections in a crossover design was not significantly different for the two routes of administration.[8] Reported subcutaneous dosages and treatment durations vary, and recommendations on the treatment regimen have also changed over time.[1,7,9–11] The

current LeishVet guidelines recommend 75–100 mg/kg every 24 hours or 40–75 mg/kg every 12 hours for a treatment duration of 28 days.[1] Reported dosage intervals vary from 8 to 24 hours, but systemic availability studies show that one dose in 24 hours is adequate.[11] Dogs with leishmaniosis without serious renal disease have a 4-year survival rate of 75% after treatment with meglumine antimoniate for 3–6 weeks, with additional treatment cycles in case of relapses.[8]

Despite the effectiveness of meglumine antimoniate, several side effects have been reported. A major reported side effect is nephropathy. Disruption of the effect of antidiuretic hormone may be the cause of temporary polyuria, as shown in rats.[12] Renal tubular necrosis may cause acute kidney injury (AKI), albeit infrequently.[13,14] Furthermore, injections may be painful and can lead to local injection site granulomas.[15,16] Another disadvantage is that the therapy is costly.[17] Also, meglumine antimoniate is chemically stable, but if handled without sterile techniques and equipment, sterility cannot be guaranteed, and it should ideally be used within 8 hours after opening the ampule.[18]

In the Netherlands, it is common practice for veterinary professionals to teach owners how to administer the subcutaneous injections themselves. This approach may be questioned, taking into consideration the difficulty of administering painful daily injections and the possibility of serious side effects such as AKI, which may not be recognised by the owner. For these reasons, owners may be reluctant to start meglumine antimoniate therapy and may choose an alternative treatment option. The aim of this study was to investigate the personal experience and impact of the treatment on owners and on their bond with their dog. A secondary aim was to assess the process and owner-assessed effectiveness of subcutaneous treatment with meglumine antimoniate in dogs with leishmaniosis in the Netherlands.

MATERIALS AND METHODS

Owners and dogs

A list of all prescriptions for meglumine antimoniate from January 2009 to December 2018 was obtained from the veterinary pharmacy of the Veterinary Faculty of Utrecht University (Netherlands). This pharmacy supplies meglumine antimoniate to all veterinary clinics in the Netherlands, including the Department of Clinical Sciences of Companion Animals (DCSCA) of Utrecht University. At initial presentation to the DCSCA, pet owners are asked to sign a treatment agreement that includes information on the privacy and use of the data of their pet. Informed consent was obtained from owners of dogs who were treated in private practice by contacting the referring veterinarian. In November 2019, an email with a link to a web-based questionnaire was sent to all owners. The email was accompanied by a short video in which one of the authors (DvE) explained the aim of the questionnaire.

Questionnaire

The questionnaire was designed in Qualtrics software. The participants were informed that the questionnaire was anonymous, and no incentive was provided to participate or finish the questionnaire. The participants could quit the questionnaire at any time. The questionnaire was divided into five sections. Section one concerned the demographics and characteristics of the studied population of owners and dogs. Section two focused on the therapy itself, with questions concerning the number of meglumine antimoniate therapy cycles, the duration of the therapy, other medications, the time between treatments and the questionnaire, who administered the injections, and therapy adherence. Section three focused on the effectiveness of the therapy as perceived by the owner of the dog. The owners were asked to score clinical signs before, during and after the treatment. The two remaining sections related to the effect of the therapy on the owner, the bond between the owner and their dog and the owner's comfort with administering the therapy (Supporting Information S1).

Owners were given the option to book a telephone consultation if they needed help completing the survey. The questionnaire was anonymous unless the participants chose to provide contact details. The questionnaire remained open for 10 weeks, and reminders were sent twice.

Data analysis

Questionnaires were analysed if at least two sections were completed. Therefore, the results are reported as proportions instead of absolute counts.

When a course of meglumine antimoniate injections had been started, it was counted as one cycle regardless of the number of days the injections were given. It was recorded if injections were given alone, with help from another person without veterinary training or by a veterinarian. If respondents had needed help with giving the injections beyond the instruction phase, the injection cycle was counted as being given by the veterinarian.

Clinical signs as perceived by the owner were scored on a four-point ordinate scale (absent, mild, moderate, severe) before, during and 1 month after the start of therapy. Scores for clinical signs before and 1 month after therapy were compared with the Wilcoxon rank-sum test. A p-value of less than 0.05 was considered statistically significant.

A five-point ordinal scale, ranging from zero to five, was used for the parts of the questionnaire focused on the impact of the course of meglumine antimoniate as perceived by the owner and the impact on the bond between dog and owner. For clarity of reading,

the results have been modified using a three-point scale, focusing on the aspect of agreement (scores 1 and 2) versus disagreement (scores 4 and 5) with the statement.

RESULTS

The study population

Meglumine antimoniate was prescribed to 87 individual dogs at least once. Sixty-four respondents (74% response rate) completed at least two sections of the questionnaire. Two of the 64 respondents completed the survey with the help of one of the authors (DvE). Not all respondents answered all questions, and responses were reported as proportions or the number of respondents per question.

Most respondents (n = 47) were between 30 and 60 years of age, five were between 30 and 39 years of age, 24 were between 40 and 49 years of age and 18 were between 50 and 59 years of age. Fourteen respondents were above 60 years of age, one respondent was between 18 and 20 years of age and two respondents chose not to answer. Fifty-one of the 64 respondents were female, 10 respondents were male and three respondents chose not to answer. Most respondents had owned their dog for more than 1 year (n = 41), 21 respondents had owned their dog for less than a year (11 dogs for 6–12 months, four dogs for 3–6 months, four dogs for 1–3 months and two dogs less than 1 month) and three respondents did not answer the question. Most dogs originated from countries endemic for *Leishmania infantum* (Spain, n = 38; Greece, n = 13; Portugal, n = 3; one each from Romania, Italy and Turkey). Five dogs originated from the Netherlands, and two respondents did not answer (NA) the question.

Twenty-eight castrated female dogs, 25 castrated male dogs, two intact female dogs, seven intact male dogs and two NA were included in the study. Their mean body weight was 19.9 kg (range 3–55 kg; n = 61). At the time of the questionnaire, 40 dogs were alive and 22 dogs had died (two NA). Six dogs died more than 3 years before the questionnaire was completed, 11 dogs died between 1 and 3 years before and four dogs died during the year leading up to the questionnaire (one NA). According to the owners, 10 dogs died as a direct result of leishmaniosis, and 11 dogs died for other reasons (one NA).

The therapy

All of the dogs had received at least one 3–4 week course of subcutaneous injections of meglumine antimoniate. Twenty-nine dogs had two or more cycles of meglumine antimoniate treatment. The maximum number of cycles reported was four. One owner could not remember the exact number of cycles of meglumine antimoniate given.

The time between the last cycle of meglumine antimoniate and the response to the questionnaire was less than 6 months for eight dogs, between 6 months and 1 year for eight dogs, between 1 and 2 years for 12 dogs and over 2 years for 36 dogs.

In 67% of the dogs (43/64), the owner administered the injection alone, whereas 19% of the owners (12/64) received help from a partner, family member or friend. In a minority of the cases (9/64), several or all the injections were given by a veterinarian. The owners of seven of these nine dogs indicated that they were regularly helped with the administration of the injections. In one case, the owner replied that the veterinarian gave the meglumine antimoniate injections on a few days when the owner was not able to give the injections. In another case, the owner found it increasingly difficult to give the injections because the dog showed a painful reaction, and they therefore asked the veterinarian to complete the course.

Fifty-seven owners answered the question regarding from whom they received the instructions for administering the injections. These owners received instructions from a veterinarian from the DCSCA (n = 12), a Dutch first-line veterinarian (n = 41), both the DCSCA and the referring veterinarian (n = 2) and, in one case, a veterinarian in Portugal (from where the dog was imported). One owner was trained as a veterinary technician and did not specify the source of the instructions. All the respondents (15/15) who answered the question agreed that the instructions for the administration of the subcutaneous injections had been either clear (5/15) or very clear (10/15). Two of them remarked that the instructions had been verbal and that the veterinarian had demonstrated how to administer the injections. In addition, nine of the 15 respondents had practised administering the injections together with the veterinarian.

Of the 24 respondents specifying the time spent giving the injections, the large majority replied that it took them up to 5 minutes (n = 17) or 10 minutes (n = 4). Two respondents replied that it took them 20 minutes.

Fifty of the 64 respondents indicated that their veterinarian prescribed a 4-week cycle of once-daily subcutaneous meglumine antimoniate injections. Of these 50 respondents, 46 completed the cycle without missing more than three injections, and one respondent missed more than three injections. In three of these 50 dogs, the owner stopped the treatment cycle prematurely; because of disease progression during the treatment cycle in two dogs and severe injection site reactions in one dog. In 14 dogs, the owners reported that the therapy plan proposed by their attending veterinarian differed from the regular 4-week cycle of once-daily subcutaneous meglumine antimoniate injections.

The owners were also asked to score the possible side effects of the meglumine antimoniate therapy on a four-point ordinal scale ranging from absent to severe (pain at injection site, nodules at injection site, hyporexia, nausea and/or vomiting, diarrhoea, lethargy, less active, decreased playfulness and stress

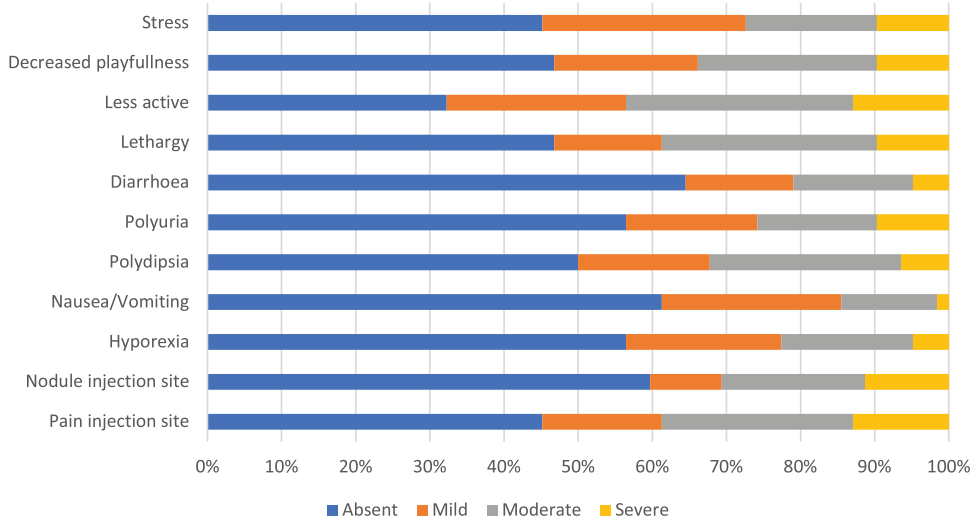

FIGURE 1 Severity of pain at injection site, development of nodules at injection site, hyporexia, nausea and/or vomiting, polyuria, polydipsia, diarrhoea, lethargy, decreased activity, decreased playfulness and stress due to therapy on days that meglumine antimoniate injections were administered, as reported by owners ($n = 62$)

during therapy). The results are given in Figure 1. Apart from being less active, which was present in 70% of dogs, each problem was reported in about 50% of dogs. Of note, owners scored both the presence of pain and the occurrence of nodules at the injection site in eight and seven of the 64 cases, respectively, as severe. Polyuria and polydipsia were reported to be severe in up to 10% of dogs. Stress due to the administration of the daily injections and the associated side effects was scored as severe in 10% of the dogs.

Effectiveness of therapy as perceived by the owner

To assess how owners perceived the effectiveness of the therapy, they were asked to score clinical signs on a four-point scale ranging from absent to severe, before and 1 month after the course of meglumine antimoniate injections (Figure 2). The scores for all clinical observations except for vomiting and eye problems had significantly decreased 1 month after therapy ($p < 0.01$).

Impact of therapy on the owner and owner–dog bond

The impact of the injections on different aspects of the wellbeing of the respondents was rated (Figure 3). Most owners neither perceived the cycle of meglumine antimoniate injections as too expensive nor felt that it had negatively impacted their social life. The majority agreed that the bond between them and their dog had not suffered. Three owners felt that there had been a negative impact on the bond with their dog. About 20% of the owners had noted a negative impact on their psychological wellbeing. Only a minority of the respondents found the treatment too intensive and not worth it (13%), and they would not recommend this therapy to other owners (11%).

Furthermore, respondents ($n = 63$) assessed the ease of administration of injections, whether they had been comfortable with the level of support and whether the benefits of the therapy outweighed the emotional and financial investments (Figure 3). In general, the owners experienced administering the injections as uncomplicated, they felt well supported by the veterinarian and they rated the course of meglumine antimoniate injections favourably. Despite these positive answers, 22% of the owners had difficulties when administering the injections, and 30% reported that they felt it was bothersome for the dog. Only two owners found their veterinarian inaccessible in case of questions. In hindsight, 16% of the owners would have liked their veterinarian to have given the daily injections. In total, 11% of the owners would have liked more veterinary support in general.

DISCUSSION

The main concern of this study was whether dog owners' acceptance and compliance are sufficient to justify the recommendation that owners administer subcutaneous injections of meglumine antimoniate to dogs with leishmaniosis themselves.

The response rate of 74% was high compared to other surveys in the veterinary field, in which response rates ranging from 13% to 33% were reported,[19–21] especially taking into account that for some respondents there was a time lapse of more than 2 years between the meglumine antimoniate injections and the completion of the questionnaire. We speculate that dog owners who choose an imported rescue dog as a pet are especially motivated to contribute to research that is of special concern to this specific group of dogs. An important part of the email invitation for the

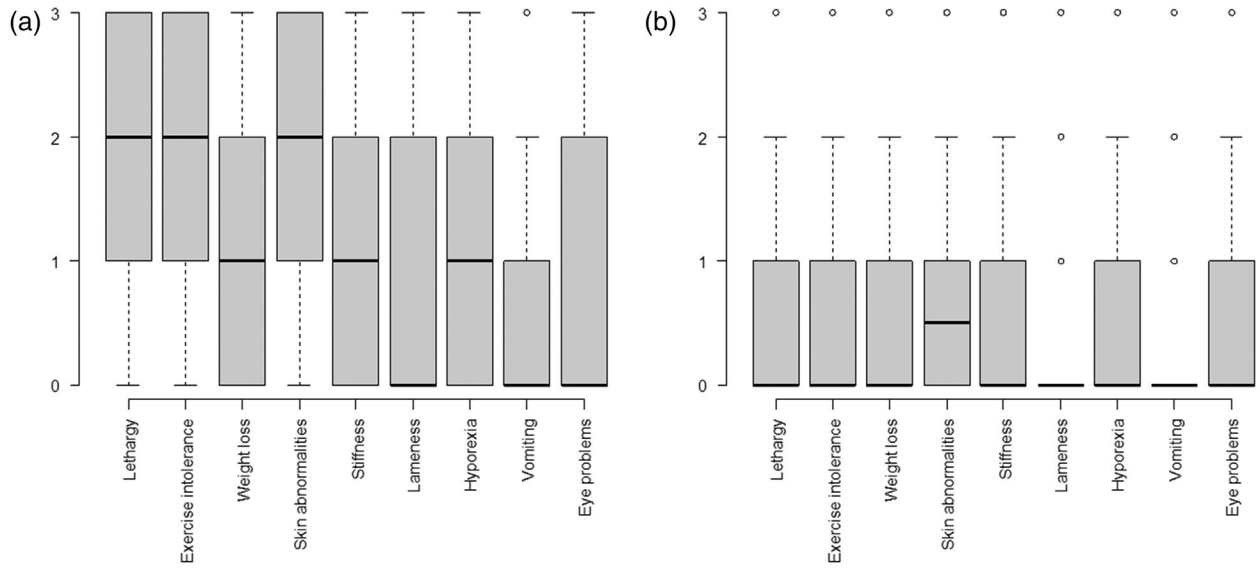

FIGURE 2 Box and whisker plots of the clinical signs as perceived by the owners ($n = 64$) before the start of the cycle of subcutaneous meglumine antimoniate injections (a) and after ($n = 62$) the completion of the injections (b). All clinical observations were scored on a four-point scale ranging from absent (0) to severe (3). The box delineates the interquartile range (IQR), and the length of the whiskers is 1.5 times the IQR. Observations outside this range are considered outliers and are represented as points. The median is represented by a horizontal line

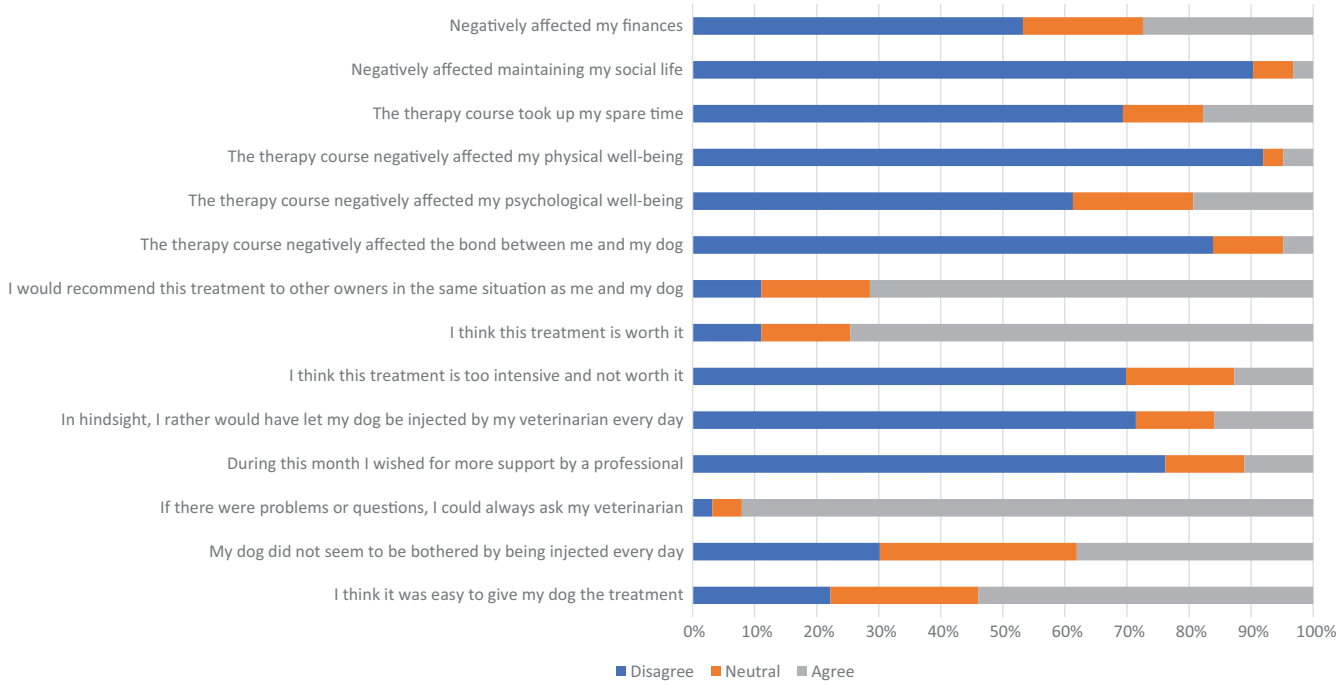

FIGURE 3 The impact of the daily subcutaneous meglumine antimoniate presented in a 100% stacked bar graph ($n = 63$). Owners were asked to report to what extent they agreed with each given statement using a five-point ordinal scale. For clarity of reading, the scale has been modified to a three-point scale ranging from disagree to agree

questionnaire was a short video in which one of the authors (DvE) explained the aim of the study to the dog owners accompanied by an adopted rescue dog. We believe that this personalised approach grabbed the attention of the respondents and contributed to the high response rate. Despite the overall high response rate, some questions had a lower number of responses, which may have biased the results. For example, 57 respondents answered the question regarding who provided the instructions for the owners, while only 15 respondents answered the question on whether the instructions were clear. All 15 respondents were positive about the clarity of the instructions. It is possible that those owners for whom the instructions were not clear did not answer this question, leading to a bias in assuming that the instructions were always clear.

We conclude that owners can administer subcutaneous meglumine antimoniate to their dogs without

major problems. Eighty-six percent of the respondents were able to administer the injections efficiently without professional help after receiving what they perceived as adequate instructions from a veterinary professional. However, problems were observed during the injection cycle, as reported by others, including pain, the development of injection site granulomas[8] and polyuria and polydipsia.[13] It is intriguing that pain and the development of nodules at the injection site are apparently perceived as acceptable by the owners. One of the explanations may be that owners are told beforehand that the injections may be painful and that nodules at the injection site can be expected. This conversation prior to the start of therapy may have introduced inclusion bias into the studied population, as some owners may have decided not to go ahead with meglumine antimoniate injections. Also, the fact that the therapy was successful (Figure 2) and the disease was potentially lethal may have put the side effects into a different perspective for the owner.

The occurrence of kidney injury is a concern during the course of a meglumine antimoniate therapy cycle. Polyuria, as perceived by the owner, was reported in our study and can be due to interference with the action of antidiuretic hormone[12] or AKI due to tubular damage, as reported in healthy dogs.[13] Our study was not developed to investigate the incidence of AKI during meglumine antimoniate treatment, but it was not mentioned by the owners as a reason why 11 dogs stopped treatment early. The fact remains that AKI is a potentially serious side effect, and there is an urgent need for veterinary intervention, necessitating veterinary supervision during the meglumine antimoniate injections and clear prior instructions to the owners on when to contact their veterinarian.

We also investigated how dog owners experienced the treatment. Although most owners had a positive perception of the treatment period, one in five respondents acknowledged that it had not been easy to give their dog the daily injections. About 10% of owners would, in hindsight, have preferred that the veterinarian had given the injections. This indicates that although most owners perceived the instructions as clear and were happy with the support, a subset of owners found it difficult to foresee the reality of what daily injections entailed.

We are not aware of other studies evaluating owner experiences with the administration of meglumine antimoniate to dogs. One study investigated the experiences of owners injecting their diabetic dog or cat with insulin, a non-irritating substance. Of the dog owners (97% of 224 included dogs were given insulin injections), 77% considered the treatment easy to perform. However, anticipatory thoughts included the inconvenience of giving daily injections (67%), fear of giving injections (66%) or worry about the reaction of the pet to injections (43%).[22] This initial uneasy feeling is also described in the human literature for at-home paediatric injections. A study concerning paediatric rheumatoid diseases found that parents often felt insecure and that a gradual increase in responsibility in giving the injections to their child was needed. The paper concluded that proper training and follow-up sessions were important.[23]

Our study has several limitations. First, memory lapse may have influenced the answers to the questions since, for many dogs, the arrival of the questionnaire was more than 2 years after the meglumine antimoniate injections, and many dogs received more than one cycle of meglumine antimoniate injections. Second, although our response rate was fairly high, adding an 'I don't know/I can't remember' option might have helped to improve the response rate. Last, there may have been inclusion bias. Meglumine antimoniate may have been preferentially prescribed to dog owners who were assessed as being capable of administering the injections. In addition, it may be that owners whose dog had died before they received the questionnaire may have been less willing to respond.

Our study showed that owners generally remain highly motivated to persevere throughout an intensive therapy cycle of meglumine antimoniate injections despite the often encountered side effects and the required emotional and time investment. Most owners do not feel that the quality of life of the dog or the owner–dog bond is negatively impacted by the daily injections of meglumine antimoniate. Based on our data, we anticipate that providing active veterinary support during the therapy cycle may further improve acceptance. Additional feedback and coaching throughout the therapy cycle might be helpful for owners. The use of, for example, instruction videos and regular telephone check-ups should be explored. The data from this study may also be used to provide accurate information for dog owners twho seek information on what to expect when a cycle of meglumine antimoniate injections is prescribed. Finally, research should focus on alternative meglumine antimoniate formulations that cause less local and renal tissue damage. For example, pentavalent antimoniate embedded in a liposomal formulation has shown promising results.[24,25]

AUTHOR CONTRIBUTIONS

Conceptualisation: Christine J. Piek, Demy van Eijk and Marja K. de Jong. *Investigation*: Demy van Eijk, Christine J. Piek and Marja K. de Jong. *Writing—original draft preparation*: Demy van Eijk, Christine J. Piek and Marja K. de Jong. *Figure preparation*: Christine J. Piek and Marja K. de Jong. *Writing—review and editing*: Demy van Eijk, Christine J. Piek, Marja K. de Jong and Femke Broere. All authors have read and agreed to the published version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare they have no conflicts of interest.

FUNDING INFORMATION

The authors received no specific funding for this work.

DATA AVAILABILITY STATEMENT

The data are available upon request from the authors.

ETHICS STATEMENT

In the project, no experiments on dogs were conducted or data were collected that met the definition of an animal experiment as laid down in the Dutch Experiments on Animals Act and EU Directive 2010/63/EU. Informed consent was obtained from all study participants.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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