Acupuncture prevents relapses of recurrent otitis in dogs: a 1-year follow-up of a randomised controlled trial

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ABSTRACT

Background  Recurrent infections within a particular, well-localised body location are often seen in veterinary and medical practice. This condition could represent a localised or segmental immune deficiency. Recurrent canine otitis seems to be one example of this problem. It has been reported that acupuncture increased the efficacy of conventional treatment for canine otitis by >50%.

Objective  To assess whether the relapse rate of recurrent canine otitis over 1 year can be modified by acupuncture in adult dogs.

Methods  One-year follow-up of a randomised controlled trial. 31 dogs with a history of recurring otitis were randomised into two groups. In addition to conventional treatment, each group received four sessions of either real acupuncture, group A (n=16), or sham acupuncture, group B (n=15). The main outcome for the follow-up was the rate of acute otitis episodes in each group over 1 year, with blinded evaluation. A χ² test was used for statistical analysis.

Results  There was one dropout in each group. Fourteen (93%) dogs in group A: were free of otitis relapses, compared with 7 (50%) in group B (p<0.01).

Conclusion  Acupuncture seems effective for preventing relapses in cases of recurrent canine otitis. This result suggests that acupuncture could be tested as a treatment of other recurrent localised infections. Given the ability of acupuncture to modulate neurotransmitters and opioid peptides, which can in turn modulate the immune system, the immune response to acupuncture also seems worth exploring.

INTRODUCTION

Recurrent infections within a particular, well-localised body zone are often seen in veterinary and medical practice. Susceptibility to relapsing infections may occur at a particular part of the body, which differs between one individual and another. It can be seen in the upper respiratory tract (sinusitis, pharyngitis, bronchitis), the digestive tract (e.g., Helicobacter pylori) or the genitourinary tract. In some cases there is no clear evidence of either structural changes or general immune dysfunction.1,2 However, this type of condition seems to behave as a localised or segmental immune deficiency, though literature on this topic is scarce.

Recurrent canine otitis externa (RCO) appears to be a suitable animal model to study this type of problem. Some surrounding changes may occur in the external auditory tract, leading to the appearance of infection.3,4 Given the unique physiology of the ear canal and the common physiopathology of otitis externa, regardless of the underlying cause, it can be a complicated and difficult disease to diagnose and treat.5 In some patients, adequate control of the acute infection sometimes fails to prevent relapse.

One may surmise that some type of neural network disturbance may occur in the affected tissue, predisposing to infections. For instance, a segmental autonomic disruption could disturb both vascular tone and tissue tropism together with sebaceous and sweat gland dysfunction, which in turn triggers the susceptibility to infection. These types of changes probably involve some degree of local tissue alteration, which upsets the external ear defence barrier, inducing a local or segmental impairment in the immune function or, simply, a segmental immune dysfunction.

Chronically infected ears usually have a similar appearance regardless of the underlying causes, often with fungal infection.6,8 In patients with RCO, different combinations of primary, predisposing and perpetuating factors often coexist. Hence, each patient’s unique therapeutic needs may be determined by careful interpretation of historical and physical findings, which should be supported by ancillary diagnostic tests.9 Conventional treatment of RCO resolves most acute cases within 1–6 weeks, but does not always prevent recurrence.10 At the end-stage of chronic disease, surgery may be indicated, but it is not always successful.11 However, there is evidence that acupuncture, a form of peripheral sensorial stimulation, elicits nociceptive inputs into the spinal cord and brain, activating central self-regulating mechanisms, which in turn could inhibit some
pathological, self-maintained, segmental reflexes. In this manner, acupuncture can relieve certain visceral or somatic dysfunctions. In the first report of this randomised controlled trial, acupuncture was more effective than sham acupuncture for acute episodes of otitis in dogs. Puncturing around the affected ear accelerated recovery of the animals and increased by >50% the efficiency of a conventional treatment (ear washing, local antiseptic ointment and systemic antibiotics) that the dogs had previously received. Acupuncture induced significant reduction of the complete recovery time (p<0.01); the time to disappearance of secretions (p<0.001) and pain (p<0.01); and the main index of visual analogue scale (VAS) score of the intensity of symptoms (p<0.001). However, when reassessed at the third month after treatment, both groups had recovered.

This follow-up of the trial was conceived in order to observe the relapse rates of the two groups. The aim of the study was to ascertain if segmental acupuncture can eventually modify the natural history of recurrent infections.

**MATERIALS AND METHODS**

This report is an account of the extended follow-up of the above-mentioned randomised clinical trial. Nevertheless, we should state that six additional animals were randomised because our initial intention was to repeat the study with a larger sample size. However, because of unexpected budgetary and manpower limitations, that plan had to be abandoned in November 1997. Thus we collected our final data in November 1998, 1 year after the randomisation of the last participant. We analysed the data in the summer of 2007.

The study setting was the Macaracuay Veterinary Clinic, Caracas, Venezuela, but in order to help the enrolment process, other veterinary clinics and other veterinarians were invited to refer patients to the trial.

When an animal fulfilled the inclusion criteria, the dog's owner was asked to read and accept the research protocol and provide informed consent. Animals from different breeds, aged 2–10 years, were enlisted in the protocol and provide informed consent. Animals from different breeds, aged 2–10 years, were enlisted in the protocol and provide informed consent.

Our null hypothesis was that the relapse rate of sham and real acupuncture groups would not differ.

**Design**

This study was a follow-up of a randomised controlled study. Randomisation without stratification was performed using a list obtained from a random number table, which was administered by phone by one of us (MSA). After an owner gave consent for their dog to enter the study, the veterinarian of the project (AP) immediately contacted MSA, who, after consulting the random list, informed him as to which group this animal should be allocated. This random allocation was made just after the first session of conventional treatment. Thereafter, AP provided the acupuncture treatments and, after the last session, did not see the animals again.

It is noteworthy that no owner knew about veterinary acupuncture and no animal had previously received it. Moreover, the owners were not present during the treatment. Additionally, apart from the clinical history, we used a code-numbered sheet to record the information about the treatment group of each animal. This information remained inaccessible to both clinic staff and owners during the follow-up. Hence, it was unlikely that they could identify the group to which the animal belonged.

All dogs received the same conventional treatment (CT) for RCO. Then, those that met the inclusion criteria were randomly assigned to one of two groups: group A received additionally a real acupuncture treatment (CT+Ac), whereas group B received sham acupuncture treatment instead (CT+5Ac).

**Ethical aspects**

We believed it was acceptable to compare real and sham acupuncture on two random groups, because we wanted to test the efficacy of acupuncture; and ascertain whether distant, extrasegmental needling might be as effective as segmental needling. Additionally, all animals received a proven conventional treatment. We did not know in advance whether acupuncture would be effective or not, as clinical trials often find no significant differences between real and sham acupuncture. Finally, animals undergoing a relapse were given the best emerging acupuncture treatment after finishing the trial.

The clinic directorate’s ad hoc ethic committee accepted the trial protocol and gave permission for the study. Also, they approved the informed consent format for the animals’ owners. We informed the owners that two types of acupuncture would be compared, one of which might eventually prove to be ineffective, though on some occasions both treatments had a similar level of efficacy.

**Inclusion criteria**

The inclusion criteria were as follows: (1) animals with an acute episode of unilateral otitis externa, with an intact tympanic membrane; (2) no more than 3 days since onset; (3) at least one previous episode of external otitis; (4) positive smear and culture for bacterial infection; (5) no other current infestation such as myasis, ticks, scabies.

Animals with bilateral otitis, or simultaneous presence of extra-auricular skin lesions were excluded, as were puppies and dogs with a first infection, dogs domiciled in another city and dogs whose owner did not accept the acupuncture treatment.
Veterinarian VAS score,† mean

Owner’s VAS score,* mean

Before first treatment

Table 1 Baseline data for acupuncture (A) and sham acupuncture (B) groups

<table>
<thead>
<tr>
<th>Baseline data</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>16</td>
<td>15</td>
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<tr>
<td>Age Mean (years)</td>
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<tr>
<td>SD</td>
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<tr>
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<tr>
<td></td>
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<tr>
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<tr>
<td></td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Others</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Before first treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Owner’s VAS score,* mean</td>
<td>44.2</td>
<td>45.8</td>
</tr>
<tr>
<td>SD</td>
<td>8.2</td>
<td>6.7</td>
</tr>
<tr>
<td>Veterinarian VAS score,† mean</td>
<td>9.6</td>
<td>10.2</td>
</tr>
<tr>
<td>SD</td>
<td>2.3</td>
<td>2.6</td>
</tr>
</tbody>
</table>

†Veterinarian VAS (0–5) score: mean value of three clinical signs assessed by the veterinarian; maximum score 15.

Assessment of otitis

The dogs’ owners assessed six symptoms or intensity of signs—namely, (A) pain (graded according to the intensity of weeping or groaning); (B) ear secretion; (C) itching (graded according to the presence and the movements of scratching or joiling of the head); (D) dog’s appetite; (E) animal’s ‘mood’; (F) sleeping habits. Those features had to be assessed both before each treatment session and, subsequently, in the case of relapse at any point over a 1-year period. Owners scored these symptoms on a VAS, graded from 0 to 10 points; 0, representing the absence of a given symptom or sign, and 10, the maximum expected intensity. The VAS values of each group were added to obtain the owner’s VAS score, with a maximum value of 60.

Veterinarian assessment

The veterinarian assessed the animal by general inspection and otoscopic examination. The following features were scored: (A) skin aspect and colour and presence of oedema (channel diameter); (B) amount of secretion; (C) pain to touch and/or to pinna manipulation. The clinical features were assessed both before each treatment session and, afterwards, in case of relapse at any point over a 1-year period. The veterinarian used a VAS graded from 0 to 5 to quantify those clinical signs. Zero described normality, whereas 5 represented, for the three criteria, abundant ceruminous or purulent secretion; epithelial inflammation or hyperplasia with channel diameter reduction; and hypersensitivity to touch. The sum constituted the veterinarian VAS score, with a maximum of 15. The first assessment outputs are presented in table 1.

Conventional treatment

Animals were hospitalised the first time for 24 h for clinical assessment, taking of laboratory specimens and instructing their owners about the process and use of VAS scales. Laboratory samples were taken of the secretion for microscopy, culture and sensitivity tests, though testing was limited for budgetary reasons. Then, standard conventional treatment was given to all dogs. This comprised washing the external ear with a solution of 50% iodopovidone in saline solution. Then an antiseptic mixture of ampicillin 75 mg/100 ml, cloxacillin 200 mg/100 ml and prednisolone 20 mg/100 ml (Mastitest) was topically applied. This was followed by intramuscular treatment with procaine penicillin, which was subsequently substituted by a more specific antibiotic according to culture sensitivity tests. The specific antibiotic was commonly kanamycin or trimethoprim, and when indicated (i.e., mycosis or yeast overinfestation established through microscopic analysis), topical ketoconazole was administered. Finally, animals were randomly allocated to one of two groups. That treatment procedure was repeated every 3 days for both groups, just before the acupuncture treatment.

Group A (real acupuncture)

The acupuncture points programme was chosen using a neurobiological approach, based on the association between a dermatome and its corresponding neural and viscerosomatic segment. In our case, it was the periauricular sensory field, C2–C3.

The acupoints TE17, TE21, SI19 and GB20 were superficially punctured around the affected ear, together with LI 4 on the ipsilateral forelimb. A veterinarian acupuncturist with 5 years’ experience administered the acupuncture treatments. One session of 15 min every 3 days was applied just after the auricular cleaning and conventional treatment session. Each dog in both groups received four sessions of conventional treatment and needling. Five needles (DN54 made by Sédatélec, France, 34 mm long and 0.4 mm wide) were used during each session. The needles were inserted up to a depth of 2–3 mm, without mechanical stimulation.

We used topographic references of classic veterinary acupuncture texts for domestic animals to choose acupuncture points. Some of their locations were extrapolated to the animal from descriptions found in human acupuncture texts, as follows: TE17, located in the depression between the mandible and the mastoid process; TE21, located in the depression facing the supratragal notch; SI19, found just in front of the central part of the ear tragus; GB20, placed on the posterior and lower part of the mastoid process, behind the insertion of the sternocleidomastoid muscle; LI4, located in the angle formed between the dog’s first and second metacarpal bones, as shown in figure 1.

Group B (sham acupuncture)

As previously suggested, the control treatment was chosen according to the same segmental approach. Five needles were superficially inserted at random points around the kneecap in the contralateral knee for...
15 min—that is, into a segmental zone far away from the area of pathology (the ear), and devoid of classical acupuncture points. No needle manipulation was performed, so as to avoid activating diffuse noxious inhibitory controls.

Blinding in the study
The details of treatment were recorded and kept separate from the clinical record of each animal; so that the staff veterinarians doctors could not see them. Additionally, owners and the staff veterinarian, when asked about which acupuncture type they believed any animal had received, did not know; so, it seems that masking had been achieved.

Main outcome
The main outcome was episodes of relapse of otitis in both groups. When otitis symptoms or signs reappeared, the dog’s owners were advised to assess the animal using the owner VAS score and to go immediately to the veterinary clinic to seek one of the trial staff. A staff veterinarian, blinded to the type of acupuncture the animal had received, assessed it and documented the new episode of otitis using the same clinical criteria and procedures. Then he reported it to one of the authors (AP), who in turn consulted the random numbered sheets in order to establish the dog’s corresponding group.

Statistical analysis
The date of disappearance of signs and symptoms, as well as that of stopping treatment, was noted for each animal; the latter was chosen as the beginning of the 1-year follow-up period. The comparison of the number of dogs that relapsed between groups was carried out through a χ² test. The accepted significance level of p was <0.05.

RESULTS
Baseline data show that the groups were comparable at the start of the trial (table 1). There was one dropout in each group. One dog in group A died in a street accident, and one in group B moved with its family away from Caracas. Thus, the numbers finally included in the analysis were group A: n=15 and group B: n=14 (table 2).

Only one dog with reinfection was seen in group A (1/15, 7%), whereas seven dogs relapsed in control group B (7/14, 50%). The difference between groups was significant (p<0.01).

DISCUSSION
Our research shows that the chances of RCO were significantly reduced by a short course of segmental acupuncture. The strength of this study resides in the fact that both owners and assessors were blinded to the dogs’ group allocation, thus avoiding biases in assessing episodes of recurrent infection during the follow-up period. The main constraint of the study was its small sample size due to lack of resources.

Since the beginning of acupuncture clinical research, it has been known that puncturing itself can be beneficial if applied in the appropriate dermatome. It has been established, though often ignored, that so-called ‘sham’ acupuncture, or minimal needling off the meridian, often has powerful specific effects. So, for the control intervention, needling at any place far enough away (at least three or four segments) from the diseased zone is a suitable form of control treatment, at least, in this type of acupuncture trial. Nevertheless, we would need to develop appropriate strategies in order to increase the credibility of the study.
while masking the ‘distant needling’ procedure as a control treatment in a human context.

On the other hand, one might deduce that segmental needling would reactivate some local, segmental and general factors underlying the defence mechanisms of the ear, leading to a reduction of relapse. Further studies with an adequate sample size are required to confirm this assumption. An understanding of the neurobiology of segmental infection recurrence may be of interest; therefore, diverse animal or human models of localised infection should be developed for that purpose.

In addition, clinical trials of sufficient sample size and with adequate immunological measurements should be designed in order to either discard or validate the working hypothesis of segmental immune dysfunction.

Nowadays, it seems well established that immune tissue behaves as a target organ of the sympathetic nervous system. The sympathetic nervous system acts as an interface between the central nervous system and the immune system. One might speculate that the effect of acupuncture operates through this route. Some publications have shown positive results for acupuncture as a treatment for recurrent urinary tract infections in adult women and also for sinusitis. Those studies, though rather rare, seem, independently, to be based on a similar hypothesis to our study.

CONCLUSIONS

Acupuncture using a neurobiological approach seems to reduce the relapse rate of canine otitis, though replication in larger studies is required to confirm this finding.

Acupuncture may act as a modulator of the immune system; therefore, further clinical research in this field, enhanced with immune measurements, would seem justified.

The results of this study may produce a new way of thinking about other recurrent infections, including those affecting human beings; however, further clinical research with immunological assessment would be necessary in order to exclude or verify the working hypothesis of segmental immune dysfunction.

Competing interests The senior author is research director of Instituto de Investigación de Salud y Terapéutica, a non-profit organisation that promotes research on complementary alternative medicine from an academic perspective.

Ethics approval Approval was obtained from the clinic directorate’s ad hoc ethic committee.

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