THE USE OF ARNICA FOR THE TREATMENT OF SOFT-TISSUE DAMAGE.

ABSTRACT: There is growing anecdotal evidence of the use of homeopathy among sports' participants. Arnica montana [also known as Leopard's Bane] is frequently used as a prophylactic agent both before and after long distance running in the belief that it reduces delayed onset muscle soreness [DOMS]. There is equivocal evidence of its efficacy. The lack of convincing scientific proof is a major reason for homeopathy not being embraced by the medical community. The aim of this review is to discuss the principles of homeopathy in general, followed by a more detailed analysis of the use of arnica in the treatment of soft tissue trauma. Clinical trials published since 1982 were identified using the

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Medline database. Based on these data it was concluded that there is no overwhelming evidence that treatment with a homeopathic remedy, specifically Arnica montana, consistently reduces the severity of, or the rate of, healing of soft tissue damage.

KEY WORDS: HOMEOPATHY, ARNICA TABLETS, DELAYED ONSET MUSCLE SORENESS, LONG DISTANCE RUNNING.

INTRODUCTION

There is growing anecdotal evidence of the use of homeopathy among sports' participants. For example arnica is frequently used as a prophylactic agent both before and after long distance running in the belief that it reduces delayed onset muscle soreness [DOMS]. Although homeopaths often use arnica for the treatment of soft tissue trauma, there is equivocal evidence of its efficacy (Lokken et al 1995; Jawara et al 1997). This lack of convincing scientific proof is a major reason for homeopathy in general not being accepted by the medical community (Lockie 1998). In contrast the alternative practitioner believes that homeopathy's long history and continued successful use worldwide demonstrates its efficacy.

Despite the differences in approach between homeopathy and conventional

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medicine, 40% of general practitioners in the Netherlands practise homeopathy and 42% of general practitioners in Britain refer patients to homeopaths (Vallance 1998). In government clinics in India, homeopathy is practiced in conjunction with conventional 'western' medicine (Vallance 1998). According to Jacobs et al (1998) the use of homeopathy is growing in the United States of America.

The aim of this review is to discuss the principles of homeopathy in general, followed by a more detailed analysis of the effectiveness of arnica in the treatment of soft tissue trauma.

ARNICA

Arnica montana, also known as Leopard's Bane (Allen 1978), is the most frequently studied homeopathic remedy in placebo-controlled trials (Ernst 1998). It is the best known of all homeopathic remedies, and most often used in cases of acute physical trauma to treat both the injury and the accompanying shock (Smith 1998) bruising and post-surgical repair (Hart et al 1997).

Arnica montana is a perennial Alpine herb with a creeping underground stem and a rosette of pale oval leaves. The flowering, erect stem is up to 60 centimeters high, bears a single, bright

yellow, daisy-like flower. The plant, which is difficult to cultivate, is native to northern and central Europe and also grows wild in Russia, Scandinavia and northern India (Lawless, 1995).

PRINCIPLES OF HOMEOPATHY

The word 'homeopathy' is derived from two Greek words, *omio* meaning 'same' and *pathos* meaning 'suffering' (Lockie 1998). Homeopathy is regarded as a naturopathic form of medicine (Vallance 1998) that aims to assist the body's healing mechanisms rather than override them (Lockie 1998).

The fundamental premise of the discipline is that a homeopathic remedy, when given to a healthy person, will produce the same symptoms as those of the ill person. The homeopathic remedy stimulates the body's innate healing ability and thereby provokes the body's system to combat these symptoms. This is analogous to the immunizations of conventional medicine that use dilutions of allergens to control the allergies themselves.

NOMENCLATURE

Homeopathic treatments are prescribed as a "D"[or "X"], or "CH" [centesimal Hahnemann] preparations. "CH" refers to the centesimal scale of the medicinal preparation where the original remedy has been diluted on a scale of one drop to 99 drops of water [1 part per 100 parts] and shaken by a process called succussion.

In the case of a CH30 preparation the whole process is repeated 30 times. The "D" [or "X"] prescription refers to a decimal scale where each dilution involves 9 drops of water to one drop of the original substance (Kaplan 1994). For example a D6 (6X) is a 1 in 10 dilution repeated 6 times which is obtainable without prescription. D30, [30X] represents a medium potency [dilution 1:10 to the power of 30, that is, succussion repeated 30 times]. According to homeopathic theory the higher the potency the greater the effect. The most commonly used dilution are 30X preparations (Lokken et al 1995).

THE BASIS OF HOMEOPATHY

The two main principles of homeopathy are the "simillimum" and "potentisation by succussion" (Reilly et al 1986). According to these principles, if the toxic effects of an agent closely mimic a patient's symptoms, the simillimum argument applies and the physiological reaction provoked by that substance in diluted and succussed amounts may aid the patient's recovery. Analogous to vaccination and immunotherapy, the simillimum principle is sometimes seen as a paradoxical drug effect. The patient is often sensitive to a homeopathic stimulus, which can aggravate symptoms initially. The principle of "potentisation by succussion" applies when the remedy is administered after an initial process of serial dilutions and succussion. The effect of the remedy may be maintained and even enhanced at "apparently absurd dilutions", [ultra-high dilutions (UHDs)] where theoretically none of the original substance remains due to the dilution and succussion process (Reilly et al 1986; Vallance 1998).

Homeopathic remedies are derived primarily from plants, minerals and metals. Substances are tested on healthy human volunteers to determine their therapeutic value. These tests are known as "provings". A prescription is only considered to be effective if the symptoms produced by the remedy during

the "provings" match changes in the health of the individual (Smith 1998). This is the basic principle of homeopathy - similia similibus curentur - like cures like. Each homeopathic substance can be appropriately used in a range of conditions, so there are a number of remedies to chose from. Conversely, a single remedy can target a wide variety of conditions. This explains the administration of commonly used, broad-based, over-the-counter remedies for a variety of conditions.

Homeopathy is based on individualized treatment, where ideally a single homeopathic medication is selected according to the signs and symptoms, temperament, disposition, personal and family history of the patient (Lokken et al 1995; Smith 1998).

RESEARCH IN HOMEOPATHY Homeopathy in General

Research on the efficacy of homeopathic remedies has been an ongoing process for over two hundred years (Koehler 1986). A summary of the clinical trials published since 1982 (identified using the Medline database) is shown in Table 1. The studies have been summarized according to the research design, the dosage and duration of treatment, the outcome variables and the results of the study. Twelve of the 14 studies included a placebo group. Of the remaining two studies, (no placebo group), one study showed that pharmacotherapy was not more effective than homeopathic treatment (Hitzenberger et al 1982) and the other study demonstrated no significant difference in bleeding times immediately following the administration of Arnica montana in a 2-period cross-over trial in healthy volunteers (Baillargeon et al 1993). Ten studies showed that the homeopathic treatment had no advantage over the placebo treatment.

The studies with an objective overview or meta-analysis design are shown in Table 2. These studies are summarized under the headings of 'study selection criteria' and 'general conclusions'. Only one of these studies (Reilly et al 1994] showed that treatment with homeopathy was more effective than treatment with placebo. Two other studies (Kleijnen et al 1991;

Barnes et al 1997) showed that homeopathic remedies tended towards being more effective than placebo, but the remaining six studies concluded that there was insufficient evidence to support any claims of homeopathic efficacy.

Therefore, it can be concluded that there is no overwhelming evidence that treatment with a homeopathic remedy, even Arnica montana reduces the severity of tissue damage or increases the rate of healing.

Effects of arnica on delayed onset muscle soreness (DOMS)

Tveiten et al (1991) assessed the effect of Arnica montana D30 on muscle stiffness, restitution time and muscle cell damage using a double-blind randomized trial following the 1990 Oslo Marathon. Blood tests were carried out before and immediately after the finish of the event, and again after 48 and 72 hours. There were differences in only two of the variables measured between the groups immediately after the finish or after 48 hours and 72 hours. The placebo group had a higher level of plasma creatine kinase [a physiological indication of muscle cell damage] 48 hours post-race. The placebo group also reported experiencing a greater degree of stiffness on all four occasions. The trial indicated that arnica did not reduce the time of restitution but seemed to reduce muscle soreness.

Jawara et al (1997) studied the effects of arnica and rhus tox on DOMS following bench stepping exercise. The authors suggested that homeopathy was an effective treatment although the data were not statistically different. Vickers et al (1997) also compared the effect of a homeopathic preparation of arnica and rhus tox CH30 and a placebo on DOMS following bench stepping. Their trial also showed that there was no difference between the homeopathic groups and the placebo group in altering the perception of muscle soreness over the five-day period.

In a further study Vickers et al (1998) conducted a randomized, double-blind, placebo-controlled trial to determine whether treatment with homeopathic arnica 30X was superior to placebo for decreasing muscle soreness following

Table 1: REVIEW OF INDIVIDUAL TRIALS.

SUBJECTS [M/F]	RESEARCH DESIGN	DOSAGE AND DURATION	VARIABLES MEASURED	RESULTS	REFERENCE
n=10 [m/f ²]	Randomized double blind cross-over	Patients with essential hypertension treated with antihypertensive pharmacotherapy or homeopathic treatment	Blood pressure	No superiority of pharmacotherapy over homeopathic treatment in decreasing blood pressure	Hitzenberger,
n=118 [m/f²]	Randomized double blind placebo controlled cross-over	Following surgical removal of impacted wisdom teeth, under general anaesthetic Oral administration 2 x day of Group 1 Metronidazole 400mg Group 2 Arnica montana 200mg Group 3 Placebo 1 tablet	Pain control on VAS Trismus [limitation of mouth opening] Prevention of swelling Promotion of healing	Metronidazole greater effect in pain control, preventing swelling, and more effective in promoting healing than arnica and placebo. Arnica group had greater pain [p<0.05] and more swelling than placebo [p<0.01]	Kaziro, [1984]
n=108 [m/f?]	Randomized double blind placebo controlled	Patients with active hayfever given a1 week run-in, baseline placebo, for analysis. Then 1 tablet placebo or homeopathic test drug [30C potency] for 2 weeks, followed by 2weeks observation	Daily VAS of over- all symptoms and intensity of sneezing, blocked and runny nose, and watery, red and runny nose. Similar details recorded by doctor at weeks 0, 3 and 5	Subjects treated with homeopathy had a significant reduction in symptom scores assessed by patient and doctor in week five [final week] p=0.02. Initial aggravation of symptoms in homeopathic group followed by improvement	Reilly et al, [1986]
u=ś	Randomized double blind placebo controlled	3 lactose tablets sublingually 4-hourly for 2 days post partum [where tearing or suturing occurred]. Thereafter 3 times a day for 3 days. 3 groups:- Group 1 D6 arnica Group2 D30 arnica Group 3 Unmedicated placebo	Perineal pain Breast pain Mood a] Mother b] Baby Perineal appearance	More subjects using arnica D30 described themselves as 'unhappy' (p<0.05). The questionnaire responses showed a tendency towards more favourable results and with arnica D6 than placebo less favourable with D30 than placebo	Hofmeyr et al,
n=36 [m/f ²]	Randomized double blind placebo controlled	Arnica C30. Five tablets twice daily for 5 days starting before 42.2km race.	Blood tests before race, at finish, 48 hours and 72 hours after race. Stiffness evaluated on [VAS] after finish and for next 3 days	No difference in the liver enzymes or creatine, haptoglobin or magnesium. Plasma CK increased in both groups but to a greater level in placebo group. Difference greatest on day 2 [p=0.07] A feeling of stiffness more pronounced in placebo group on all 4 tests [p=0.06 and 0.07 on day 2 and 3]. No indication that arnica decreased time of restitution	Tveiten et al, [1991]
n=101 [m=66 f=35]	Randomized, double blind placebo controlled 3 groups [athletics injuries]	Group 1 Traumeel S ointment Group 2 Traumeel Sine ointment. [Both contain 1.5g of arnica D3 in 100g ointment] Group 3 Placebo. No arnica. Ointment base without the Medicinally active ingredients]. First medication not later than day 4 post injury. Thereafter selfapplication twice daily until day 15. 6 to 10 mg each application	Primary criteria - abatement of swelling and normalisation of skin temperature Secondary criteria - 1] maximum muscle force 2] pain index 3] time interval for resumption of training without complaints	No difference between two Traumeel ointments when tested on 5th and 15th day Difference [p<.0001] between these and placebo on 15th Day 1] Maximum muscle force: Both Traumeel groups superior to placebo on day 15 but not day 5 2] Pain index: Both Traumeel groups superior to placebo day 5 and 15 3] Resume training: Both Traumeel groups superior to placebo	Bohmer and Ambrus, [1992]

Abbreviations:

► Continued on page 37.

m = male, f = female, VAS = visual analogue scale, ? = data unavailable, DOMS = delayed onset muscle soreness

SUBJECTS [M/F]	RESEARCH DESIGN	DOSAGE AND DURATION	VARIABLES MEASURED	RESULTS	REFERENCE
n=?	2-period cross-over trial	Arnica Montana in healthy volunteers	Bleeding times and the impact on various blood coagulation tests immediately following administration	No significant effect	Baillargeon et al, [1993]
n=28 [m/f ²]	Randomized double blind placebo controlled	4 weeks, single blind placebo. Then daily dosage for 8 weeks- Group 1 oral homeopathic immunotherapy to their principal allergen Group 2 identical placebo [no homeopathic substance]	Daily VAS of overall symptom intensity	Difference in favour of homeopathic immunotherapy within 1 week of treatment and persisting up to 8weeks [p=0.003]	Reilly et al, [1994] See meta- analysis table
n=24 [m=4 f=20]	Randomized double blind placebo controlled cross-over	3 tablets [containing 6 homeopathic drugs at D30 potency, including arnica] or placebo given 3 hours post op. for surgery on 1 side for bilateral impacted wisdom teeth and continued for 5 days. Following identical surgical procedure on opposite side 14 to 51 days later, crossover tablets administered	Pain on VAS Swelling, trismus, and bleeding	No positive evidence for efficacy of homeopathic treatment on pain and other inflammatory events	Lokken et al, [1995]
n=60 [m/f?]	Randomized double blind placebo controlled	First month baseline, all patients on placebo. Thereafter test group on Individualized homeopathic Prophylaxis	Frequency and severity of migraine attacks	No difference at baseline. No difference between placebo and homeopathic group thereafter	Whitmarsh et al, [1997]
n=73 [m=0 f=73]	Randomized double blind placebo controlled	2 doses arnica C30 tablets or placebo 24 hours pre-op. Then the morning after total abdominal hysterectomy, 3 doses/day for 5 days of arnica or placebo	on VAS every	No difference between placebo and homeopathic group on postoperative recovery	Hart et al, [1997]
n=50 [m/f?]	Randomized double blind placebo controlled	1 tablet arnica C30 and rhus tox C30] orally 3 times a day 24 hours prior to bench stepping exercise. Continued until subject felt no muscle soreness Placebo group	DOMS evaluated on VAS scale every 12 hours for 7 days	No difference between placebo and homeopathic group [p>0.2]	Jawara et al [1997]
n=67 [m=23 f=34]	Randomized, double blind placebo controlled	1 tablet 3x/day orally of a complex of arnica C30, rhus tox C30 and Sarcolactic acid Placebo group	Muscle soreness scored on Likert scale 5 days after 10 minute bench- stepping exercise	No difference between placebo and homeopathic group	Vickers et al, [1997]
n=400 [m/f?]	Randomized, double blind placebo controlled	Arnica C30 group Placebo group	Muscle soreness scored twice daily on Likert scale for the 5 days following long distance racing	No difference between placebo and homeopathic group	Vickers et al, [1998]

Abbreviations:

m = male, f = female, VAS = visual analogue scale, ? = data unavailable, DOMS = delayed onset muscle soreness

Table 2: REVIEW OF META-ANALYSES (From 1990).

NO. OF STUDIES	STUDY SELECTION CRITERIA	CONCLUSIONS	REFERENCE
n=40 (total of 523 subjects)	40 published randomised trials: results of the homeopathic treatment were compared to those of a standard treatment, placebo, or no treatment	Results did not provide acceptable evidence that homeopathic treatments are effective	Hill and Doyon, [1990]
n=107		81 of 105 trials with interpretable results, were positive regardless of the quality of the trial or the variety of homeopathy used. Evidence of clinical trials is positive, but not sufficient to draw definite conclusions because most trials were of low methodological quality and unknown publication bias	Kleijnen et al, [1991]
n=213		Medline and Embase searches give an "impression" of the evidence	Kleijnen and Knipschild, [1992]
n=3 (total of 202 subjects)		The effects of homeopathy were greater than placebo [p=0.0004]	Reilly et al, [1994]
n=6 n=776 [cases]		Evidence that homeopathic remedies=/<12C [but not=/>12C] can reduce time to first flatus after abdominal or gynaecological surgery [p<0.05]	Barnes et al, [1997]
n=89		Insufficient evidence that homeopathy is effective	Linde et al, [1997]
n=32 (total of 1778 subjects)]		Individualized homeopathy has effect over placebo. Evidence however, not convincing - methodological shortcomings and inconsistencies	Linde and Melchart, [1998]
n=8.		The claim that homeopathic arnica is effective over placebo is not supported by rigorous clinical trials	Ernst and Pittler, [1998]
n=? (not described)		Homeopathy perceived to be ineffective for any type of low blood pressure	Ernst and Pittler, [1999]

long distance running. Four hundred subjects completed a visual analog and Lickert scale of muscle soreness twice daily for the five days following their race. The authors concluded from their results that arnica was not effective in reducing muscle soreness after long distance running (Vickers et al, 1998).

DISCUSSION AND CONCLUSION

The aim of this review was to describe the general principles of homeopathy followed by an analysis of the research on the efficacy of homeopathic treatment, specifically *Arnica montana*. It is clear from the data in Tables 1 and 2 that there is no convincing evidence that treatment with a homeopathic remedy consistently reduces the severity of, or increases the rate of healing of damaged tissue.

Some homeopathic remedies are diluted to the point where there can be no remaining molecules present to explain their proposed biological effects. The use of Ultra High Dilutions [UHDs] appears to many scientists to make homeopathy a scientific absurdity. According to Vallance (1998) most scientists reject UHD effects because of their intrinsic implausibility in the light of current scientific understanding. Lokken et al (1995) question whether

the infinitesimally diluted substances used in homeopathy really exert biological activity and Vandenbroucke (1997) argues that the 'infinite dilutions' of the agents used cannot possibly produce any measurable effect. Their scepticism is supported by the absence of any scientific proof of such activity (Lockie 1998). Yet others, such as Endler and Schulte (1994), believe that UHDs have an effect, relying on the accepted homeopathic concept of 'hormesis', the belief that high concentrations of a homeopathic agent suppress, while low ones stimulate healing. In an editorial comment, Davenas et al (1988) uses the argument that an aqueous solution of a homeopathic substance retains its ability to elicit a biological response even at such high dilutions where there is negligible chance of a single molecule remaining in any sample. This is based on the concept that dilutions are followed by vigorous shaking [succussion], and the transmission of the biological information could be related to the molecular organization of water (Davenas et al 1988).

The studies evaluated in table 1 and 2 were designed according to the classic scientific rationale of an experimental group receiving the treatment, and a control group receiving a placebo. However, this goes against the basic edict of homeopathy, where prescriptions are highly individualized to meet the needs of the patient. As Koehler (1986) points out, double-blind trials are unacceptable for establishing the efficacy of homeopathic remedies because, in accordance with homeopathic principles, the individual reactivity and receptiveness of the subject must be taken into account and the dose attenuated accordingly. According to Rivett (1999) double-blind, placebo-controlled clinical trials should not be regarded as the only acceptable evidence of a treatment or drug's therapeutic value. Smith (1998) is of the opinion that the inappropriateness of the randomized clinical trial model for the individualized prescription is now being overcome with the development of new double-blind protocols that are more patient orientated.

In summary, scientists are taught to evaluate evidence according to a set of rules (double blind placebo type studies). Homeopathy, due to the reasons described, precludes an evaluation using a double blind placebo design. To be examined and judged by the scientific process, an alternative system to the conventional system must be used. Until this happens, homeopathy will be viewed with scepticism by scientists. At present scientists have proved (using their rules) that homeopathy does not work. The responsibility would appear to be that of the homeopaths to establish a set of rules that is acceptable to the scientific community and which can be used to evaluate homeopathic treatment.

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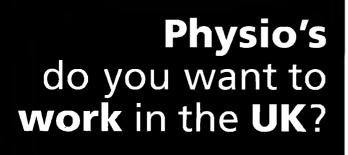
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