ARNICA AND THE TREATMENT OF SOFT TISSUE TRAUMA

By
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DECLARATION

I, Cynthia Moira Bauer, do hereby declare that neither the substance nor part of this thesis has been submitted in the past, or is being, or is to be submitted for a degree in the University or any other University. The work on which this thesis is based is my original work.

This thesis is presented in partial fulfilment of the requirements for the degree of Master of Philosophy (Sports Physiotherapy). Departments of Physiotherapy and MRC/UCT Research Unit for Exercise Science and Sports Medicine, Department of Human Biology; Faculty of Health Sciences, University of Cape Town.

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INTRODUCTION

The word "homeopathy" is derived from two Greek words, *omio* meaning "same" and *pathos* meaning "suffering". Homeopathy is regarded as a naturopathic form of medicine that aims to assist the body's healing mechanisms rather than override them. 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 which the ill person complains. In accordance, 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.

In summary, homeopathy is based on individualized treatment, where ideally a single homeopathic medication is selected according to the patient's signs and symptoms, temperament, disposition, personal and family history.

Arnica montana [also known as Leopard's Bane], is the most frequently studied homeopathic remedy in placebo-controlled trials. 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, bruising and post-surgical repair. There is no overwhelming evidence that treatment with a homeopathic remedy, specifically *Arnica montana,* consistently reduces the severity or increases the rate of healing of the damaged tissue.

There is growing anecdotal evidence of the use of homeopathy among sports' participants. Arnica is frequently used as a prophylactic agent both before and after long-distance running with the belief that it reduces delayed onset muscle soreness [DOMS] which is soft-tissue trauma (Jawara *et al*, 1997).

However, the specific details of its use among athletes has not been quantified. Furthermore,

the scientific evidence supporting the efficacy of arnica for treating muscle damage is not clear. This thesis attempts to address both these questions.

The thesis is written as two parts. The aim of the first part is to review the literature and discuss the principles of homeopathy, followed by a more detailed analysis of studies on the efficacy of arnica for treating soft tissue trauma. The second part of the thesis is a study designed to investigate the usage patterns of arnica tablets amongst runners in the 1999 ninety-kilometre Comrades marathon.

CHAPTER 4

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]. However 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 an analysis and meta-analysis of the literature on the use of arnica and homeopathy in the treatment of soft tissue trauma. A systematic search of clinical trials of arnica and homeopathy, and studies based on meta-analysis published since 1982 were identified using the Medline database. In order to clearly identify and define the search, the Medline database was chosen as this is a comprehensive database of journals which have a high probability of publishing peer reviewed papers on arnica, homeopathy and muscle damage. 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]. Arnica is commonly used for any type of soft tissue damage (Jawara *et al*, 1997).

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 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 practised 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 literature of the effectiveness of arnica in the treatment of soft tissue damage.

METHODS

A systematic search of clinical trials of arnica and homeopathy, and studies based on meta-analysis published since 1982 were identified using the Medline database. In order to clearly identify and define the search, the Medline database was chosen as this is a comprehensive

database of journals which have a high probability of publishing peer reviewed papers on arnica, homeopathy and muscle damage.

ARNICA

Arnica montana [also known as Leopard's Bane], (Allen, 1978), is the most frequently studied homeopathic remedy in placebo-controlled trials (Ernst and Pittler, 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 and 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 natropathic/allopathic form of medicine (Vallance, 1998) that aims to assist the body's healing mechanisms rather than override them (Lockie, 1998). It 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 (Locken *et al*, 1995; Smith, 1998). Homeopaths choose the prescription according to the severity of the signs and symptoms of the above (personal communication with Dr. Denise Robinson, homeopathic doctor at Weleda [Pharma Natura, Wynberg, Johannesburg]). The more severe these signs and symptoms are,

the stronger the potency of the homeopathic remedy given. In severe cases a homeopath would consider a CH30 medication. This is more potent because it has been succussed and "diluted" to a greater extent than a D6 [also referred to as 6X] which is used for a milder condition. This is the purist approach, which is regarded as very accurate (personal communication with Dr. Ian Sanne, medical doctor and consultant for Pharma Natura, and who is involved in research in homeopathy at the University of Witwatersrand).

A more generalized method is the use of a broad based, less specific and less potent homeopathic remedy, such as D (or X) which can be bought over-the-counter (this can also be used in a randomized study using a large number of subjects).
As in conventional 'western' medicine there is controversy about, and many different approaches by practitioners for dosages and treatments.

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 remedies are "D"[or "X"], or "CH" [centesimal Hahnemann] preparations (Kaplan, 1994; Koehler, 1986; Lockie, 1998). "CH" refers to the centesimal scale of the 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"] 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 over-the-counter. 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. 30X preparations are the most commonly used dilution (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. If the remedy is potentised by repeated mechanical shock (succussion) at each stage in a series of dilutions, 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 remedy is only considered to be effective if the symptoms produced by the remedy in the healthy individual during the "provings" match changes in the health of

the symptomatic individual (Smith, 1998). This is the basic principle of homeopathy - *similia similibus curentur*- like cures like. In accordance with this principle 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.

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). Summaries of the clinical trials published since 1982 (identified using the Medline database) are 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.

All 14 studies included a placebo group. Nine of the studies used arnica. The remaining 5 studies used a "homeopathic" remedy. Three trials demonstrated a difference in results in favour of homeopathy (Reilly *et al,* 1986; Bohmer and Ambrus, 1992; Reilly *et al*, 1994). The study by Hofmeyer *et al* (1990) showed a "tendency" that arnica D6 had better results than placebo, but arnica D30 was less favourable than placebo. In the study by Hitzenberger *et al*, (1992) (double-blind, placebo controlled, cross-over) the effects of antihypertensive pharmacotherapy were compared to those of homeopathic treatment in 10 patients with hypertension. The blood pressure lowering effect under pharmacotherapy was superior to that under homeopathy. The study by Baillargeon *et al* (1993) aimed to test whether *Arnica montana* significantly decreased bleeding time or had a significant impact on various parameters of blood coagulation in healthy volunteers. The results showed that it did not have

a significant effect [page 19, Table I of thesis]. Kaziro (1984) showed that metronidazole was more effective than arnica and placebo in pain-control, prevention of swelling and promoting healing. Tveitan *et al, (*1991) found that arnica C30 tablets were more effective in reducing stiffness than placebo after 48 hours and 72 hours after completion of a 42.2 kilometer race. However blood tests showed no advantage over placebo. Seven studies showed that the homeopathic treatment had no advantage over the placebo treatment (Baillargeon *et al*, 1993; Lokken *et al,* 1995*;* Whitmarsh *et al,* 1997; Hart *et al,* 1997; Jawara *et al,* 1997; Vickers *et al,* 1997; Vickers *et al,* 1998).

Nine studies with 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.

Therefore, it can be concluded that there is no overwhelming evidence that treatment with a homeopathic remedy 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 both in a 30C potency or a placebo on a double-blind basis on DOMS following bench stepping exercise. Rhus tox is a homeopathic remedy indicated for stiffness which worsens at rest but is relieved by exercise which is a characteristic feature of DOMS (Jawara *et al*, 1997). The authors suggested that homeopathy was an effective treatment from placebo 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 long distance running. Four hundred subjects completed a visual analog 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), state that UHDs have an effect, relying on the accepted homeopathic concept of 'hormesis', 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] in their preparation, 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 (where neither the observor/s or the subjects know whether they are receiving the remedy or the placebo) 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 and have a more individualized perception.

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, such as a series of case controlled studies, must be used. Until this happens, homeopathy will often be viewed with scepticism by scientists. At present scientists have proved (using their rules – double-blind, placebo-type studies) 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.

TABLE 1 REVIEW OF INDIVIDUAL TRIALS

SUBJECTS [M/F]	RESEARCH DESIGN	DOSAGE AND DURATION	VARIABLES MEASURED	RESULTS	REFERENCE
n=10 [m/f?]	Randomized Double blind Cross-over	Patients with essential hypertension treated with antihypertensive pharmacotherapy or homeopathic treatment	Blood pressure	Superiority of pharmacotherapy over homeopathic treatment in decreasing blood pressure	Hitzenberger, [1982]
n=118 [m/f?]	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 a 1 week run-in, baseline placebo. for analysis. Then 1 tablet placebo or homeopathic test drug [30C potency] for 2 weeks, followed by 2 weeks observation	Daily VAS of overall 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]
n=?	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 with arnica D6 than placebo and less favourable with D30 than placebo	Hofmeyr et al, [1990]
n=36 [m/f?]	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 self-application 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]

n=?	2-period Double-blind Cross-over	*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?]	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 significant benefit of homeopathy over placebo	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	Pain and discomfort on VAS every 12 hours beginning 12 hours pre-op. Maximum 10 assessments per patient.	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 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 on a VAS twice daily 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	Published randomised trials where 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	Trials included those with parallel index and control groups and those with crossover designs. Studies in animal models were excluded	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	Controlled clinical trials on the efficacy of three interventions: homeopathy, ascorbic acid for the common cold, and ginko biloba for intermittent claudication and cerebral insufficiency.	Medline and Embase searches give an "impression" of the evidence but only if the references in the articles are followed for further evidence	Kleijnen and Knipschild, [1992]
N=3	Trials of patients with allergic asthma randomly allocated oral homeopathic immunotherapy to their principal allergen or identical placebo	The effects of homeopathy were greater than placebo [p=0.0004]	Reilly et al, [1994]
N=6	Trials using homeopathic treatment versus placebo for time to first flatus	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	Trials of double-blind and/or randomized placebo controlled versus homeopathic treatment of clinical conditions	Insufficient evidence that homeopathy is effective for any single clinical condition	Linde et al, [1997]
N=32	Randomized or quasirandomized controlled clinical trials comparing an individualized homeopathic treatment strategy with placebo, no treatment, or another treatment	Individualized homeopathy has effect over placebo. Evidence however, not convincing – methodological shortcomings and inconsistencies	Linde and Melchart, [1998]
N=8.	Placebo controlled trials of homeopathic arnica of all trials from inception to October 1997 retrieved from MEDLINE, EMBASE, CISCOM and COCHRANE LIBRARY	The claim that homeopathic arnica is effective over placebo is not supported by rigorous clinical trials	Ernst and Pittler, [1998]
N=? (not described)	A postal questionnaire survey based on computerised searches to systematically identify by objective criteria 50 clinical experts' opinion on the efficacy of alternative therapies for low back pain.	Homeopathy perceived to be ineffective for any type of low back pain.	Ernst and Pittler, [1999]

ABBREVIATIONS

N =number of studies

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CHAPTER 5

THE USE OF ARNICA TABLETS BY RUNNERS IN THE 90-KILOMETRE COMRADES MARATHON

ABSTRACT

Background: Arnica is a homeopathic remedy which is sometimes used before and after long-distance running in the belief that it reduces delayed onset muscle soreness (DOMS). Physiotherapists are frequently asked about the efficacy of arnica tablets and the recommended dosages. However, the specific details of its use among athletes is not known. Therefore the aim of this study was to determine the usage patterns of arnica tablets amongst participants in the 1999 ninety-kilometre Comrades ultra-marathon road race in South Africa. *Methods:* Every third runner registering for the race in Pietermaritzburg in the three-day (25 hour) pre-race registration period was approached and asked to complete a questionnaire on their use of arnica tablets (n = 785; males = 85% and females = 15%). *Results:* Ten percent of the total study population who agreed to participate in the study (n = 730) had used arnica tablets in the previous six months. The average reported dose by these athletes was seven tablets per day. The most common reason for using arnica tablets was to decrease pain or stiffness after a race or training run. Only a small group (22%) rated the efficacy of arnica tablets as "totally effective", and this suggests that a large number of users of arnica tablets did not rate the efficacy highly. There was a poor relationship between the perceived efficacy after ingesting arnica tablets and the reported dosage (r = 0.28). The majority of the respondents (63%) believed that arnica tablets contained anti-inflammatory agents. *Conclusions*: While ten percent of the runners used arnica tablets, only one fifth of these runners rated the treatment as completely effective for the prevention of DOMS. Therefore education on the advantages and disadvantages of using these tablets has become important.

KEYWORDS: ARNICA TABLETS, LONG-DISTANCE RUNNING, MUSCLE SORENESS, HOMEOPATHY

INTRODUCTION

There is growing anecdotal evidence of the use of homeopathy amongst sports' participants, in particular long-distance runners and other endurance athletes. Patients frequently ask physiotherapists about the ingestion of arnica tablets and their efficacy in preventing or minimizing delayed onset muscle soreness (DOMS). Therefore, this is a relevant question which should be investigated to enable physiotherapists to have an evidence-based answer for these questions. Arnica tablets are frequently used as a prophylactic agent both before and after long-distance running in the belief that the treatment reduces DOMS. However, although homeopaths often use arnica tablets for the treatment of soft tissue trauma, there is equivocal evidence of its efficacy (Lokken *et al,* 1995; Jawara *et al*, 1997). One viewpoint is that homeopathy's long history and continued successful use worldwide convincingly demonstrates its efficacy in the treatment of injuries and wounds (Lokken *et al* 1995). An alternative viewpoint is that the lack of convincing scientific evidence is a major reason that homeopathy is generally not accepted by the medical community (Lockie, 1998). Despite the discrepancy between the viewpoints of the practitioners of homeopathy and medicine, the use of homeopathic remedies, among them arnica tablets, is still widespread. No studies could be found to establish details on the use of arnica tablets.

Therefore the main aim of this study was to determine the prevalence of usage of arnica tablets in a group of ultra-endurance athletes. A secondary aim was to determine the perceptions of its efficacy and constituents, dosage and the most commonly used commercial brand in this group of runners. This may serve to determine whether the reasons for using arnica tablets are matched by their purported effects.

METHODS

Ethical approval for the study was obtained from the Ethics and Research Committee of the Faculty of Health Sciences, University of Cape Town. It was felt that the relevancy for physiotherapists was to investigate the incidence of usage amongst runners, from whom those users had heard/been advised to use arnica tablets, how many tablets they took per day, how long a period they had used them and their perception of what they contained. This would assist physiotherapists in answering their patients' questions. Prior to targeting runners registering for the 1999 Comrades marathon, the questionnaire was evaluated in a pilot study administered to 63 marathon runners who were members of a Johannesburg running club, whereafter poorly constructed and/or ambiguous questions were identified and modified. Registration for the 1999 Comrades marathon took place at two venues during the three days before the race. An attempt was made to target every third runner registering in Pietermaritzburg. Nine people (three were supervisors) targeted the runners. Except for the busy shift in the last 4 hours of the third day, six people took shifts of 3 or 4 hours. The three supervisors shared longer shifts. This was felt to be an acceptable randomized method for this study. Finances and logistics limited the targeting to every third runner. These runners were approached and asked to complete the questionnaire. The name, Comrades marathon 1999 race number and gender of those runners who declined to complete the questionnaire were recorded where possible. Some of these runners refused to answer these sections. Where the name or race number was given, the non-responder's age, Comrades 1999 time, personal best (PB) Comrades time and number of Comrades medals was accessed on the Comrades web-site.

The sample group was divided into the following subgroups: runners who agreed to answer the questionnaire versus those runners who declined, male versus female, and runners who had previously heard of arnica tablets versus runners who had not. Those runners who reported

having previously used arnica tablets were further analysed as a subgroup. They were required to answer questions on their perceptions on the efficacy of arnica tablets and the constituents of the tablets, and their dosage used. The efficacy of arnica tablets was assessed by asking the subjects to evaluate their efficacy on a scale of "0" (absolutely no) to "7" (absolutely yes).

Data are expressed as absolute values, percentages and means (standard deviation [SD]). The Chi squared statistic was used to determine significant differences between groups for the prevalence data. An independent *t*-test was used to determine differences between groups for all parametric variables. A Spearman's correlation coefficient was calculated to determine the relationship between the dosage of arnica tablets and the perceived efficacy of the treatment. Statistical significance was accepted as $P < 0.05$.

RESULTS

The general characteristics of the total study population and sub-populations are shown in Table I. The total respondent population was n = 730 (male 85%, female 15%). Twenty-nine percent of this population had heard of arnica tablets previously (males 22%, females 7%). This represents 26% of the male population and 50% of the total female population when the data were stratified for gender.

According to those runners who had heard of arnica tablets, the most common brand was Weleda (51%), followed by Pharma Natura (20%), Bioforce (7%), and "other" (4%). The respondents were allowed to indicate more than one brand. Twenty-four percent of the subjects were not able to identify a specific brand. Of those subjects who had heard of arnica tablets, 34% (n = 72) had used them in the previous six-month period. This represents ten percent of the total sample of runners who responded. These data are summarized in Table II. There was

a significantly higher prevalence of use among female (69%) compared with male (31% $P<0.05$) respondents.

Those runners who had used arnica tablets previously were advised from a variety of sources (Table III). Respondents frequently indicated that they were advised from more than one source. The common sources in this study population were other runners (28%), physiotherapists (11%), homeopaths (11%), pharmacists (8%) and doctors (7%). Twenty-eight percent had been advised by another source, of which "wife" was the most frequent (6%) in this sub-group.

The main reasons for which the respondents used arnica tablets are depicted in Table IV. Respondents could indicate more than one reason. The most frequently reported reasons were to minimize pain and stiffness after a run/race (61%) or to reduce pain/stiffness before a run/race (41%). Four percent of the respondents used arnica tablets to improve their ability to train harder while 11% used arnica tablets for "other" reasons. Arnica tablets were also used for conditions unrelated to running (36%) of which eight percent listed "sore muscles". Only 22% of those runners who had used arnica tablets previously regarded their effects to be completely effective while one percent found them to be totally ineffective. Thirty-three percent of the subjects were ambivalent when asked about the efficacy.

The runners who had used arnica tablets took an average of seven tablets per day for an average of seven days. Nineteen respondents (26%) who had used arnica tablets ingested more than seven tablets a day and scored their efficacy as 80%. Forty-one subjects (57 %) took less than seven tablets a day and scored their efficacy as 71%. Twelve users (17%) did not respond to this question. The relationship between the dosage and perceived efficacy of arnica tablets was poor ($r = 0.28$).

Runners believed arnica tablets contain various substances. The commonest perceptions were that arnica tablets had anti-inflammatory properties (63%), contained 'anti-swelling' agents (38%) and pain relievers (17%). Eleven percent responded to "other" as a constituent, and 19% did not know the answer to this question. No runner listed "stimulants" as a constituent of arnica.

Fifty-five of the runners (seven percent of the total study population who were approached) declined to fill in the questionnaire. Data, which were obtained for 36% of these non-respondents, were their age, 1999 Comrades marathon time, Personal Best (PB) Comrades marathon time and total number of Comrades marathons completed (Table V). There was no significant difference in these parameters between those who answered the questionnaire and those who declined to answer the questionnaire (Table V).

DISCUSSION

The main aim of this study was to determine the prevalence of usage of arnica tablets in a group of ultra-endurance athletes using a self-reported questionnaire. Data obtained from self-reported questionnaires are open to criticism because the responses are difficult to validate. For this reason, the questionnaire was tested in a pilot study. Any ambiguous or misinterpreted questions were adjusted accordingly. The targeted runners completed the questionnaires in a controlled environment where every third runner (including those in the "green number" group who had run ten or more Comrades marathons and had a separate entry venue) registering for the 1999 Comrades ultra-marathon over the three-day registration period was approached to answer the questionnaire. The method of gathering data was believed to be valid. Furthermore, the sampling procedure was designed to select subjects in a systematic way to avoid bias. The

targeted runners who declined to answer the questionnaire had similar population demographics compared to those runners who answered the questionnaire. Therefore, it is reasonable to assume that the results of the runners who responded to the questionnaire in this study are an accurate representation of the study population (Comrades marathon runners).

The main finding of the study was that ten percent of the total study population had used arnica tablets in the previous six months and 29% of the total respondent study population had heard of arnica tablets. Furthermore, women were more likely than men to have been aware of, or to have used arnica tablets. Another finding of the study was that only 22% of the subjects who had used arnica tablets previously rated their effects as completely effective. This finding can be interpreted in two ways. Either the treatment is ineffective in most cases, or arnica tablets are not being used is the correct dosages or potencies. A fundamental principle of homeopathy is that one remedy does not necessarily help every patient with a similar complaint. Homeopathy is based on individualized treatment, where ideally a single homeopathic medication is selected according to the patient's signs and symptoms, temperament, disposition, personal and family history. The therapeutic objective of homeopathy is to treat the individual and the whole body and not just the specific condition (Koehler, 1986). Classically, homeopathy is based on individualized treatment with drugs and doses selected according to the signs, symptoms and individual temperament of the patient - factors which are not accommodated in the standard research protocols of science and medicine (Weight, 2000). This principle poses a problem for conducting a scientific, double-blind, placebo-controlled study, making the evaluation of the efficacy of arnica tablets difficult. As a result there is no consensus on the efficacy of arnica in the literature. For example, Tveitan *et al* (1991) assessed the effect of *Arnica montana* D30 tablets on runners competing in the 1990 Oslo marathon. Those runners ingesting arnica tablets experienced less

muscle stiffness, and had less muscle damage after the race as shown by lower plasma creatine activity. However, there was no difference in the duration of soreness between this group and the group who took the placebo. It was concluded from this study that arnica tablets did not reduce long-term muscle damage but did reduce acute muscle soreness. In another study, Vickers *et al* (1998) conducted a randomized, double-blind, placebo-controlled trial on 519 long-distance runners to determine whether treatment with arnica 30X tablets decreased DOMS more effectively than placebo following long-distance running. Results obtained from 400 runners and based on the fact that the runners' perception of post-exercise pain was not decreased in the control group, led them to conclude that arnica tablets were ineffective in reducing muscle soreness. Therefore, based on these data there is no justification to recommend arnica tablets before and after long-distance racing.

It is interesting to note that despite the lack of clinical trial data, and the low (22%) perception of efficacy in our study, ten percent of the runners still chose to use arnica tablets. This can perhaps be attributed to the recent surge in consumer interest and acceptance of alternative medicine, which has resulted in a tendency to self-medicate without due regard or knowledge of the advantages and disadvantages of arnica tablets.

In conclusion, ten percent of the runners in a major event in South Africa make use of arnica tablets. Only one fifth of these runners rate the treatment as completely effective for the prevention of DOMS, and therefore, education on the advantages and disadvantages of using these tablets has become important. Ultra-endurance athletes need further education on the use of arnica tablets, as their expectations are not matched by the purported affects of the homeopathic agent. Based on the data from this study there appears to be no justification to recommend arnica tablets before and after long-distance racing. Future research should

determine whether the consumption of arnica tablets should be reduced because of the poor efficacy or whether the poor efficacy is a result of incorrect usage patterns.

Tables

TABLE I Characteristics of the study population.

	Respondents	Declined*	Total
Males	623 (85%)	54 (98%)	677 (86%)
Females	107 (15%)	1(2%)	108 (14%)
Total	730	55	785

*These runners declined to answer the questionnaire and participate in the study.

TABLE II Prevalence of Arnica tablet users in the study population (n=730)

	Users	Non-users	Total
All respondents	72 (10%)	658 (90%)	730
Genders			
Males	22 (31%)		
Females	50 (69%)*		

*Significantly higher in female compared with male ($P<0.05$)

Table III The source from those respondents who had heard of arnica tablets (n = 72)

Source of advice	Number	%
Other runners	20	28
Physiotherapists	8	11
Homeopaths	8	11
Pharmacists	6	8
Medical doctors	5	7
Other	20	28
(Wife	4	6)

(Respondents could indicate > than 1 source. Not all respondents answered this question)

TABLE IV Reported reasons for using Arnica (n=72)

Reported reason	%
Used after a race/run to minimize pain/stiffness	61%
Used before a race/run to minimize pain/stiffness	41%
To improve the ability to train harder	4%
Other purposes related to running	11%
Purposes unrelated to running	36%
"Sore muscles" not related to running	8%

(Respondents could indicate > than 1 source. Not all respondents answered this question)

TABLE V Data of the runners who declined to fill in the questionnaire (36% of the total non-respondents) compared to the respondents. The sample size (n) varies depending on the number of responses to the questions.

	Non-respondents		Respondents	
Variable	n	Mean ± SD	n	Mean ± SD
Age (years)	(20)	38 ± 9	(730)	38 ± 9
Comrades 1999 time (min)	(19)	544 ± 77	(568)	576 ± 69
Comrades PB (min)	(20)	528 ± 79	(645)	542 ± 76
Number of medals	(20)	5 ± 4	(646)	6 ± 5

(PB = personal best time)

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SUMMARY AND CONCLUSIONS

Arnica is a homeopathic remedy which is sometimes used before or after long-distance running. It is thought to reduce delayed onset muscle soreness (DOMS). The study (Chapter 5) aimed to determine the usage patterns of arnica tablets amongst participants in the 1999 ninety-kilometer Comrades ultra-marathon road race in South Africa. Every third runner registering for the race in Pietermaritzburg in the three-day (25 hour) pre-race registration was approached and asked to complete a questionnaire. Prior to targeting the runners the questionnaire was evaluated in a pilot study whereafter poorly constructed and/or ambiguous questions were modified. It was decided not to include questions about other treatments. It was felt that runners might be resistant to answering a questionnaire which was not simple or longer than one page.

Physiotherapists have an important role to play in informing runners about muscle damage, pain, homeopathy, and arnica tablets in particular. The recent surge in consumer interest in, and the acceptance of alternative medicine has resulted in a tendency to self-medicate without due regard or knowledge of arnica tablets. Ultra-endurance athletes need further education on the use of arnica tablets, as their expectations are not matched by the purported effects of the homeopathic agent.

Scientists are taught to evaluate evidence according to a set of rules (double-blind, placebo-type studies) which minimizes researcher bias and experimental error. Scientists have proved using these rules that the efficacy of homeopathy is limited. The purist approach in homeopathy precludes an evaluation using a double-blind, placebo design. It is based on individualized treatment, where according to the "purist" principles of homeopathy, a single

homeopathic medication is selected according to the signs and symptoms, temperament, disposition, personal and family history of the patient.

There are many different approaches towards treatments, dosages and research methodology by practitioners of non-conventional medicine. Therefore, it is difficult to evaluate homeopathy according to the accepted scientific set of rules. An alternative system of evaluation must be used instead of the conventional system. Therefore, the responsibility would appear to be that of the homeopaths to establish a set of rules that can be used to evaluate homeopathic treatment and is acceptable to the scientific community. Until this happens, scientists will often view homeopathy with some scepticism.

APPENDIX

MRC/UCT BIOENERGETICS OF EXERCISE RESEARCH UNIT

SPORTS SCIENCE INSTITUTE OF SOUTH AFRICA

All answers will be treated confidentially

Subject No.						

Please tick correct answer.

1. NAME:													
2. DATE OF BIRTH	**Y**	**Y**		**M**	**M**		**D**	**D**					
3. 1999 COMRADES RACE NUMBER:													
4. GENDER	**Male**				**Female**								
5. When did you run your first standard marathon?	**19**								**Y**	**Y**			
6a). Have you heard of arnica **TABLETS**?	**Yes**				**No**								
6b). If **"YES"** which brand?	Weleda		Natura		Bioforce		Other		Don't know				

7. From whom have you heard about arnica **TABLETS**? (Tick more than one if necessary.)

	a) Dr.		**b)Physiotherapist**		**c) Homeopath**		**d)Pharmacist**
	e) Runner		**f) Advert**		**g) Other (specify)**		

8. Have you used arnica **TABLETS** in the last six months?	Yes		No

If "NO" thank you for your time.

9. Who advised you to use arnica **TABLETS**? (Tick only one.)

	a) Dr.		**b)Physiotherapist**		**c) Homeopath**		**d)Pharmacist**
	e) Runner		**f) Other (specify)**				

10 For what purpose did you use arnica **TABLETS**? (Tick more than one if necessary.)

a)	To improve ability to train harder?	
b)	To minimize pain/stiffness before a run/race?	
c)	To minimize pain/stiffness after a run/race?	
d)	Injuries/conditions unrelated to running?	
e)	Other (specify)	

If you used arnica TABLETS for RUNNING

11. Did you find arnica **TABLETS** to be effective for the purpose you were taking them?

Absolutely NO --→	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**←--Absolutely YES**

12. How many arnica **TABLETS**, on average, did you take everyday?

2	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**18**	**20**	**22**	**24**	**More**

13. How many days did you take the above dose?

14. What do arnica **TABLETS** contain? (Tick more than one if necessary.)

a)	**Pain reliever**	**d)**	**Stimulants**
b)	**Anti-inflammatories**	**e)**	**Anti-swelling agents**
c)	**Don't know**	**f)**	**Other**

Thank you

MANUSCRIPTS FROM THE THESIS

Bauer CM, Weight L, Lambert M 2001 The use of arnica tablets by runners in the 90 kilometre Comrades marathon. *The South African Journal of Physiotherapy* 57:14-17

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