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Effect of Warm Epsom Salt Pack over Knee Osteoarthritis-A Randomized Controlled Trial

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Authors' contributions

This work was carried out in collaboration among all authors. Author RR designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Author SD managed the analyses of the study. All authors read and approved the final manuscript.

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ABSTRACT

Aims: Osteoarthritis, the most common form of arthritis which commonly affects weight-bearing joints like the knee, hip, spine, and joints. Since the effectiveness of conventional medicine on severe types of osteoarthritis is surgical intervention, the patients are seeking alternative medicine. A warm Epsom salt pack is used commonly for pains over joints. Hence this study is undertaken.
Study Design: Randomized Controlled Trial.
Place and Duration of Study: Department of Naturopathy, SDM College of Naturopathy and Yogic Sciences, between November 2019 and January2020.
Methodology: From the inpatient department of Shri Dharmasthala Yoga and Nature cure Hospital Shanthivana, hundred subjects diagnosed with osteoarthritis belonging to the age groupof35to75yearswererecruitedandwererandomlyallocated to case (Warm Epsom salt pack) and control group. Subjects were assessed for Goniometry, Visual analog scale (VAS), Shortform-12(SF-12), Western Ontario and McMaster Osteoarthritis Index Scale (WOMAC) before and after the intervention of 20 minutes.

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Results: The study was done to evaluate the effect of Warm Epsom salt on Knee Osteoarthritis. There were 100 subjects in the sample. Shapiro-Wilk's test/Quantile-Quantile (QQ) plot was used to check the normality of variables. In study group there was a significant decrease in Goniometry (p=<0.0001), SF 12 (p=<0.0001), WOMAC (P=<0.0001). In the control group, other than VAS there were no significant changes in other variables (Goniometry, WOMAC, SF-12).
Conclusion: Our study indicates that a warm Epsom salt pack may reduce pain, stiffness, range of motion, and improves the quality of life. The study revealed that Warm Epsom salt reduced Range of motion from 172.94 to 134.5, WOMAC from 65.94 to 26.38, and Quality of life from 33.98 to 31.22. Results reveal with significant improvement (p<0.001) in pain, swelling, and quality of life.

Keywords: Warm epsom salt pack; naturopathy; osteoarthritis; range of motion.

ABBREVIA-TIONS

OA : Osteoarthritis,
WOMAC : Western Ontario,
CAM : Complementary and Alternative Medicine
VAS : Visual Analogue Scale,
SF-12 : item Short Form Survey,
GBD : Global Burden of Disease,
DALY : Disability Adjusted Life Years,
NSAID : Non Steroidal Anti-Inflammatory Drugs
MMP : Matrix Metallo Proteinases,
GFBP : Insulin Like Growth Factor Binding Protein

1. INTRODUCTION

Osteoarthritis is a diverse condition that damages the pivotal areas of synovial joints, and forms the basis for the destruction of the underlying bone, with mild synovitis [1]. Globally It is the 6th leading cause of disability leading to restricted movements. In 2020 it has been predicted to be the 4th leading cause for the poor quality of life among the geriatric age group [2]. Osteoarthritis (OA) is a chronic degenerative disease that pilots structural and biochemical changes of the synovial membrane and joint capsule with multifaceted etiology.

Signs and Symptoms of OA gradually worsen by age where clinical symptoms present with pain, tenderness, stiffness, loss of flexibility, swelling, difficulty in walking, climbing stairs, and while squatting [3]. Radiographic findings of OA reveals joint space narrowing (>3mm) over the medial tibio femoral compartment or in the patella-femoral region. On X-ray, the cardinal features include subchondral sclerosis, hypertrophy of bone, subchondral Cysts, changes in femoral condyles, and tibial plateau. MRI reveals joint effusion/ synovitis, Subchondral bone marrow edema or cysts, and cartilage defects [4]. According to the 2016 Global Burden of Disease (GBD) data for non-communicable diseases identified that the disability-adjusted life years (DALYs) for musculoskeletal conditions increased by 61.6% between the years 1990 and 2016, In which OA accounts for a 104.9% rise in DALYs from the year 1990 to 2016 [5].In India, OA is the second most common rheumatologic problem with a prevalence of 22% to 39% [6]. OA is associated with both Modifiable and Non-modifiable risk factors like obesity, sedentary lifestyle, genetic predisposition, bone mineral density, functional injury, trauma, and gender [7]. OA is more often in women than in men, but the generality increases with age. 45% of women over the age of 65 years have symptoms of knee pain, while 70% of women show radiological evidence of those over the age of 65 years. The probability factors which increase the symptoms of OA are age, female gender, overweight, functional knee posture, hereditary factors, ethnological, traumatic knee, hypovitaminosis D, and chondrocalcinosis [8]. The disability is more complex in females at the age of menopause. Osteoarthritis of the knee is a major cause of immobility, particularly among females [9,10]. Knee osteoarthritis activates a vicious cycle .The pain felt over the knee joint limits mobility and exercise, thus increasing body weight, and weight-related co morbidities. So, a multidisciplinary approach is needed to treat osteoarthritis knee joints.

Permanent therapeutic alternatives, according to the American College of Rheumatology, are out of reach for the average person, who instead turns to NSAIDs (non-steroidal anti-inflammatory medicines), which can cause kidney damage and gastric ulcer illness. To some extent, topically administered NSAIDs are also useful, so there is some assistance in evaluating and implementing the effects of these drugs.

To treat the patient's discomfort, other modalities such as exercise and olive oil applications are used. The advanced stage of OA is when the

inflammatory processes have caused abnormalities that are unable to cure. As a result, the rapid rise in the prevalence of OA will result in a situation in which physical disability reduces quality of life and increases the risk of morbidity, which is also associated with a major challenge for developing low-resource public health systems, such as those in India, and will be a significant financial burden on the country's economy. Mental health, occupation, physical activity, and socio-demographic characteristics that are essential as co-morbidities had limited data. Treatment for OA aims to minimise inflammation and pain while also increasing joint function and overall quality of life. Arthroplasty is indicated for advanced OA (joint replacement) [11].

According to studies, 40 percent of osteoarthritic patients benefit from complementary and alternative medicine (CAM) [12]. CAM is a vast domain of curative resources that encompasses all types of health systems and practices that aren't part of a society's or culture's politically dominant health system [13]. Naturopathy is a non-invasive treatment modality that includes Diet therapy, Yoga therapy, Mud therapy, Hydrotherapy, Massage, Acupuncture, Chromo therapy, and Magneto therapy. It is defined as a system of man building in harmony with constructive principles on physical, mental, moral, and spiritual planes of being [14].

Hydrotherapy is a type of a Naturopathy treatment. External or internal application of water at various temperatures, pressures, durations, and locations, as well as diverse modes of application (water, ice, steam) for health promotion or treatment of various disorders. Water used at various temperatures enhances blood flow, which is thought to help annihilate all chemicals and facilitate muscle relaxation [15]. By lowering peripheral edema and suppressing sympathetic nervous system activity, the hydrostatic effect may support in relieving pain [16]. Hipbaths, Enemas, Hot and Cold Fomentation, Hot Footbaths, Spinal baths, Steam bath, Immersion baths, and sophisticated modalities like whirlpool tubs, sprays, and jets are all forms of hydrotherapy [17].

Epsom salt also called as Magnesium Sulfate which has soothing effects helps to maintain the proper functioning of muscles and nerves within the body, as well as it maintains bone and joint health. Scientists through researches have learned that the best way to get magnesium into the body is by topically applying it through the skin [18]. It increases blood circulation by which it reduces swelling and pain around the joint thereby having anti-inflammatory and anti-arthritic properties [19]. Most people suffer from hypo-magnesium, which can affect nerve, muscle, and enzyme function, ultimately contributing to pain and inflammation, according to the Epsom Salt Council [20].

A Visual Analogue Scale (VAS) is a measurement tool that attempts to assess a pain or attitude that is thought to run throughout a continuum of values and is difficult to measure directly [21]. A new knee goniometer of the direct-attachment electromechanical type is described, and a computional technique for quantifying the total relative motion of the lower leg relative to the upper leg is developed [22]. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a disease and joint specific instrument, developed for the evaluation of knee and/or hip osteoarthritis (OA) [23]. The SF-12 is a multidimensional generic health-related quality-of-life assessment. Because of its shortness and psychometric performance, it has become frequently utilised in clinical trials and routine outcome assessments, although it cannot be employed in economic evaluation in its current form [24].

Therefore, the study was conducted to evaluate the effect of Warm Epsom Salt Pack over Knee Osteoarthritis for 10 days.

2. MATERIALS AND METHODS

2.1 Subjects

Hundred subjects with the age ranging from 35 to 70 years were recruited in the study. They were screened through medical check-up and those satisfying diagnostic criteria for Osteoarthritis were randomized into two groups.

2.2 Description of the subjects

The study population was selected from Sri Dharmasthala Manjunatheshwara (SDM) College of Naturopathy and Yogic Sciences, Ujire, Dakshina Kannada. Out of 150 subjects, 100 were recruited for the study based on inclusion and exclusion criteria.

2.3 Inclusion Criteria

The following inclusion criteria would be the basis for selecting subjects: Subjects diagnosed with osteoarthritis of the knee, according to the

American College of Rheumatology Diagnostic Criteria for osteoarthritis of the knee will be included in this study

- Both males and females
- Age 35 to 70 years.

2.4 Exclusion Criteria

Subjects who did not meet the inclusion criteria and who have the following were excluded from study

- Rheumatoid arthritis, fibromyalgia, recurrent or active pseudo-gout, cancer or other serious medical condition
- History of kidney or liver failure
- Patients who take Non –Steroidal Anti-Inflammatory Drugs (NSAID'S)
- Oral steroids within the last four weeks
- Patients who took Intra articular hyaluronate injections within the previous 6 months
- Arthroscopy of the knee within the previous year
- Significant injury to the knee within the previous 6 months
- Rash or open wound over the knee

The patients who met these criteria were eliminated from the study.

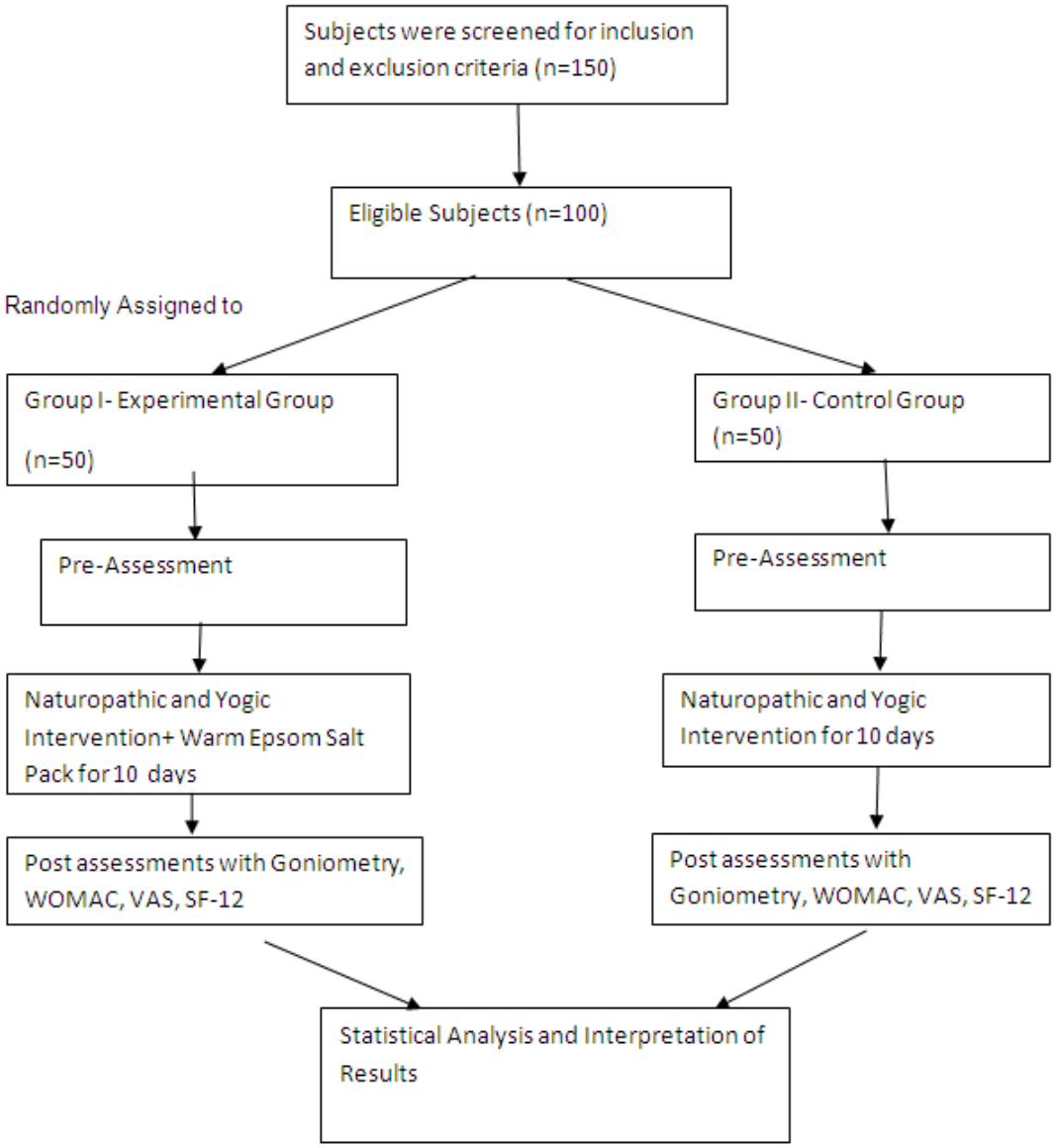

Chart 1. Illustration of study plan

2.5 Study Setting

- Study groups and randomization:
- Recruited subjects who fulfilled the inclusion criteria were divided equally into 2 groups by using computer-generated randomization. Group 1 (n=50) received Naturopathy and Yoga intervention with a warm Epsom salt pack whereas group 2 (n=50) received Naturopathy and Yoga intervention like Hydrotherapy, Mud therapy, Massage therapy Diet therapy, Yoga therapy and Acupuncture.

2.6 Design

- Study design: A Randomized controlled trial
- All the subjects received intervention for a duration of 10 days. Assessments were done on1st and 10th day.

3. STATISTICAL ANALYSIS

The study was done to evaluate the effect of Warm Epsom salt on Knee Osteoarthritis. Data is analyzed using R software version 4.0.2 and Excel. There were 100 subjects in the sample. Shapiro-Wilk's test/Quantile-Quantile (QQ) plot used to check the normality of variables. If variables are normal t-test is used for between group comparison and paired t-test used for within group comparison. If variables are not normal Wilcoxon rank sum test is used for between group comparison and Wilcoxon signed rank test is used within group comparison p-value less than or equal to 0.05indicates significance.

4. RESULTS OF THE STUDY

In case group there were 29 male patients and 21 female patients with the mean age of 47.02 years and in control group there were 24 male patients and 26 female patients with the mean age of 43.38 years.

The results of the pre-post comparisons for both the groups are detailed below:

Experimental Group: There was a significant decrease in Goniometry (P=<0.0001), SF 12 (P=<0.0001), WOMAC (P=<0.0001)

Control Group: In control group there were no significant changes in Goniometry,SF-12, WOMAC.

Table 1. Comparison of variables within and over groups (experimental and control group)

		Group		p value
		Experimental	**Control**	
Age		47.02±9.73	43.38±11.89	0.0969*t*
Gender	Male	29	24	0.4229*Ch*
	Female	21	26	
VAS	Pre	8.18 (7,10)	8.2 (7,10)	0.9226*Wr*
	Post	8.18 (7,10)	5.04 (2,7)	<0.001*Wr*
	Difference		3.16(2,8)	<0.001*Wr*
	p value		<0.0001*Ws*	_
GONIOMETRY(Degree)	Pre	133.8±14.87	134.5±14.65	0.813*t*
	Post	172.94±6.89	134.5±14.65	<0.0001*t*
	Mean decrement	39.14±15.98		<0.0001*t*
	p value	<0.0001*pt*		_
SF-12	Pre	33.28±1.41	33.28±1.41	1*t*
	Post	33.98±1.08	31.22±1.17	<0.0001*t*
	Mean decrement	-0.7±1.52	2.06±1.61	<0.0001*t*
	p value	0.0009*pt*	<0.0001*pt*	_
WOMAC	Pre	83.1±13.04	51.1±13.69	<0.0001*t*
	Post	65.94±17.65	26.38±7.73	<0.0001*t*
	Mean decrement	17.16±24.28	24.72±15.26	0.0659*t*
	p value	<0.0001*pt*	<0.0001*pt*	_

Abbreviations: Wr: Wilcoxon rank sum, Ws: Wilcoxon signed rank t: t-test, pt: paired- ttest, Ch: Chi-sq test

Table 2. Inter group comparison of pre- test and post- test of study group

	Study group		p-value
	Pre-test	Post-test	
VAS	8.18	8.18	
GONIOMETRY	133.8	172.94	<0.0001
SF-12	33.28	33.98	0.0009
WOMAC	83.1	65.94	<0.0001

Table 3. Inter group comparison of pre and post test of control group

	Control group		p-value
	Pre-test	Post-test	
VAS	8.2	5.04	<0.0001
GONIOMETRY	134.5	134.5	-
SF-12	33.28	31.22	<0.0001
WOMAC	51.1	26.38	<0.0001

By two sample t-test, there is no significant difference between , mean of Goniometry pretest and SF-12 pretest over the groups(Study & Control).By paired t-test, mean of Goniometry pretest, SF-12 pretest is significantly less than Goniometry post-test, SF-12 post-test in Study group. By paired t-test, mean of SF-12 pretest is significantly more than SF-12 post-test in Control group and mean of WOMAC pretest is significantly more than WOMAC post-test for both the groups. By one tailed two sample t-test, mean of GONIOMETRY post test, SF-12 post-testis significantly more in study group compared to control group.By one tailed two sample t-test, mean of WOMAC pre & post-test is significantly more in study group compared to control groups. By Wilcoxon signed rank test, population of VAS pretest is significantly more than VAS post-test in Control group. By one tailed Wilcoxon rank sum test, population on VAS post-test is significantly more in study group compared to control group. There is no significant difference between population of VAS pretest over the groups by Wilcoxon rank sum test. By Wilcoxon signed rank test, population of VAS pre & post test are identical in Study group. By paired t test, mean of Goniometry of pre & posttest are identical in Control group.

5. DISCUSSION

The aim of the study was to assess the Effect of Warm Epsom Salt pack on knee osteoarthritis. The result of the experimental group showed that there was a significant decrease in Goniometry, SF 12, WOMAC when compared to control group where VAS was not relevant to the study.

This was a randomized controlled trial with a sample size of 100 subjects who were randomly allotted to experimental and control groups. The assessments were done by Goniometry, WOMAC, SF-12, and VAS. There were no adverse effects reported during or after the intervention.

A study reported by Ruby Anitha et al., (2015) to assess the effectiveness of Epsom salt fomentation on knee joint pain, knee swelling and activities of daily living among elderly. It was one group pre-test post-test experimental design with 30 samples. Results reveals with significant improvement in pain, swelling and activities of daily living after 5 days of therapy [25].

Fioravanti A, Tenti S, Giannitti C, Fortunati NA,Galeazzi M. (2013) conducted a prospective randomized , single blind controlled trial to evaluate the effectiveness of Epsom salt compress in 60 outpatients with bilateral pain divided into two groups with experimental group treated with 12 daily generalized thermal baths with magnesium sulfate and normal mineral water for control group for a duration of three months the study results confirmed that Epsom salt bath had a beneficial effect in patients with joint OA [26].

The pain relief may be due to the temperature of water on the skin, according to gate theory. Pain may be relieved due to the effect of pressure and temperature on nerve endings [27].

Water immersion induced an increase in methionine-encephalin plasma levels and conversely, suppressed plasma beta endorphin, corticotrophin and prolactin levels [28]. Soaking

in an Epsom salt bath is one of the most effective means of making the magnesium your body needs readily available. Epsom salt also delivers sulfates, which medical research indicates are needed for the formation of brain tissue, joint proteins and the mucin proteins that line the walls of the digestive tract. When the Epsom salt bath is taken it has been observed that the heat generated in the water helps increase the circulation of the blood and reduction of the swelling caused in arthritis. Magnesium in the Epsom salt is known to possess anti-inflammatory and anti-arthritic properties.

However, all the symptoms for allodynia and hyperalgesia decreased after treatment with MgSo4. Moreover, studies reported increase in the concentration of glutamate in the synovial fluid in the arthritic condition of the inflamed knees. When the amount of magnesium is less in the body, this glutamate binds to the NMDA (N-methyl-D-aspartate) receptors which lead to allodynia and hyperalgesia. On treatment with Mg 2+ it was observed that these ions had preventive effect on the binding of glutamate to these receptors. In addition to thus, the researchers reported that the deficiency of magnesium ions can lead to up regulation of the interleukins 1 and 6 (IL-1 and IL-6), cytokines and inflammation in the joints. It was reported in a study that increase in the IL-1 can lead to bone cancer in animal models by up regulating a factor known as p-NR1. Thus, our study indicates that warm Epsom salt pack may reduce the pain, stiffness, range of motion, and improves quality of life. The study revealed that warm Epsom salt reduces the pain score from 8.18 to 5.04, range of motion from 172.94 to 134.5, WOMAC from 65.94 to 26.38 and quality of life from 33.98 to 31.22 . Results reveals with significant improvement in pain, swelling and quality of life. Hence it can be suggested that warm Epsom salt pack induces relaxation to the muscles, ligaments and joints by the release of local vasodilators, hormonal regulation, chemical effect through mineral absorption. These might be the mechanisms underlying the beneficial effect of warm Epsom salt pack on knee osteoarthritis.

6. CONCLUSION

The results of our study indicate that Warm Epsom Salt Pack on Knee Osteoarthritis may reduce the pain, stiffness, range of motion, and improves quality of life. The study revealed that Warm Epsom salt pack reduced the pain, range of motion, WOMAC and Quality of life.

Hence, Warm Epsom Salt Pack can be effectively employed in the management of knee osteoarthritis without any side effects. Further its application can help to improve the quality of life and reduce the disability index of the world.

CONSENT

Subjects who fulfilled the inclusion criteria were shown an information sheet having details regarding the nature of the study and intervention to be used. Subjects were given enough time to go through the study details mentioned in the information sheet. They were allowed to ask any questions and if they agree to participate in the study they were asked to sign the informed consent form which was mainly provided in the English language. All expressed their willingness to participate in the study by giving signed informed consent.

ETHICAL APPROVAL

Approval was obtained from Institutional Ethical Committee, as all tests were essentially non-invasive.

STRENGTH OF THE STUDY

The study was conducted with a sample size of 100 inpatients with a randomized controlled trial which is the strength of this study.

LIMITATION OF THE STUDY

In this study proper imaging techniques was not taken to know the stages of knee osteoarthritis.

SUMMARY

The aim of the study was to evaluate the effect of Warm Epsom Salt Pack on Knee Osteoarthritis. The total sample size was 100, in which 50 were experimental group and 50 were control group. In experimental group, patients received Warm Epsom Salt pack with naturopathy and yogic intervention whereas in control group patients received naturopathy and yogic intervention alone. The results showed that Warm Epsom salt pack over knee osteoarthritis may reduce the pain, stiffness, range of motion, and improves quality of life. The study revealed that warm Epsom salt reduced the pain score from 8.18 to 5.04, range of motion from 172.94 to

134.5, WOMAC from 65.94 to26.38 and quality of life from 33.98 to 31.22 with significant improvement($p<0.001$) in pain, swelling and quality of life. Therefore warm Epsom salt pack can be effectively employed in the management of knee osteoarthritis without any side effects.

FURTHER IMPLICATIONS

1. For Early intervention and to prevent deformity and economic loss for individual family and country Mass screening is necessary.
2. Simple life style changes such as walking, yoga, healthy dietary habits leads the community, osteoarthritis knee joint deformity free.
3. Osteoarthritis knee joint needs further research with the therapeutic treatment in order to prevent further surgeries, so it will benefit the patient and prevent the global burden.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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