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Jenna Srebnik

Philadelphia College of Osteopathic Medicine, Jennasr@pcom.edu

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Does balneotherapy effectively reduce non-specific chronic low back pain in adults?

Jenna Srebnik, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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In

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Department of Physician Assistant Studies
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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not balneotherapy effectively reduces non-specific chronic low back pain in adults.

STUDY DESIGN: Review of three single blind, follow up randomized controlled trials (RCT), published in 2012 and 2005.

DATA SOURCES: Three peer reviewed RCTs were found using PubMed and all compared balneotherapy against various control groups.

OUTCOMES MEASURED: Low back pain of patients was assessed using dose of analgesic consumed, visual analog pain scale (VAS) and Oswestry Low Back Pain Disability Questionnaire (OSWDQ). The tools used to assess significance of outcomes measured were P-values, change in mean from baseline, and SD.

RESULTS: Balogh (2005) found statistically significant reduction in VAS of both the treatment and the control group ($p < 0.01$) and the change in analgesic dose for balneotherapy group was at a significance of $p > 0.2$ compared to the control group; $p > 0.3$. Tenfer (2012) demonstrated statistically significant outcomes in all three parameters for the balneotherapy group compared to the control group that had no significant pain reduction. Kesiktas (2012) also reported statistically significant results in all three parameters analyzed.

CONCLUSIONS: The results of the RCT's reviewed demonstrate balneotherapy an effective treatment for reducing chronic low back pain. Balneotherapy may also be considered as an adjunct to physical therapy and medical management. Further research is needed to determine length, frequency and mineral composition that may provide the most significant reduction of chronic low back pain in adults.

KEY WORDS: Balneotherapy, low back pain

INTRODUCTION

Chronic low back pain is one of the most prevalent health complaints and causes of disability in industrialized nations today. Throughout a lifetime, about 80% of the population will have experienced low back pain due to a variety of causes.² Some of the common causes of low back pain in this population are; lumbar sprain and strain, vertebral infection, vertebral compression fracture, ankylosing spondylitis, herniated disc, spinal stenosis, osteoarthritis, obesity, poor posture or congenital deformity.⁵ Low back pain is a frequent complaint in all specialties of medicine, in which the pain can be described as acute or chronic. When this pain lasts greater than 3 months the pain becomes classified as chronic and patients may start to see negative impact on their psychological health, occupational life, and personal level of functioning.^{3,2,1}

It is reported that there are 19 million office visits per year for low back pain.⁴ Often times, these office visits may be followed by an expensive diagnostic work-ups and treatments including; X-ray, MRI, medications, medical admissions, physical therapy and surgical procedures, all contributing to the \$20 billion in direct costs per year.⁶ Considerable indirect costs due to absence from work, decreased productivity in the workplace, caregiving assistance and transportation are also attributable to low back pain.⁴

Individuals with low back pain admit to limitation of range of motion, decreased functionality, work performance, and general quality of life.² The pain and limitation in this population is often due to compression of nerve roots in the lumbar region from both inflammation and structural impingement.⁴ Many of the treatment modalities, that have been designed to combat low back pain, focus on this very pathophysiology. Some examples of medical treatment options that reduce non-specific low back pain are; Acetaminophen, NSAIDS,

Cox-2 specific inhibitor, muscle relaxants, corticosteroid injections, topical capsaicin cream, methylsalicylate, and glucosamine chondroitin⁵. In addition to medical options, some physical treatment options that may reduce low back pain are; flexion/extension exercises, yoga, water aerobics, TENS, chiropractor, and acupuncture⁵. Surgical treatments include discectomy, laminectomy and spinal fusion⁵ Most individuals who experience chronic low back pain require many attempts of various treatments and a combination of different modalities before their low back pain has been reduced and often the success or failure of the treatment varies greatly among individuals.⁵ Although all of these treatment options for chronic low back pain exist today, there is currently no accepted “gold standard”, which allows for research in the field to continue.

Balneotherapy, is an ancient therapeutic method that utilizes the mineral content of water through absorption as well as the buoyancy and temperature of the water to deliver analgesia and anti-inflammatory benefits.^{3,2} The exact molecular science supporting the process of how the minerals decrease pain and inflammation is still currently being researched.^{1,2,3} However, the beneficial effects of balneotherapy on specifically musculoskeletal disorders such as rheumatoid arthritis, osteoarthritis and fibromyalgia, have been published in promising science-based reports. This particular selective EBM review will evaluate three single blind randomized controlled follow up trials that evaluates the efficacy of balneotherapy as a therapy for improving non-specific chronic low back pain in patients.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not balneotherapy effectively reduces non-specific chronic low back pain in adults.

METHODS

Randomized control trials were selected based on a population of men and women with nonspecific low back pain for 3 month or longer between the ages of 40-80 years old. Articles were considered if they compared balneotherapy mineral water as an intervention to reduce low back pain to a control group such as tap water or physical therapy. The degree of low back pain was assessed using a combination of VAS, consumption/dose of analgesic required and OSWDQ. Under these criteria, three single blind RCT follow up studies were identified and included in this review.

A detailed search through PubMed using the key words, Balneotherapy and low back pain were utilized. All articles were published in English in peer-reviewed journals no earlier than 1999. Inclusion criteria consisted of randomized controlled trials with a population of men and women older than 40 who experienced back pain for at least 3 months duration. Those articles excluded had participants younger than 40 years old, adults with acute back pain and comparison groups other than tap water or physical therapy. The summary of statistics used were, P-value, standard of deviation, change in mean from baseline and t-test value. Table 1 below includes the demographics of the included studies.

Table 1: Demographics and characteristics of included studies

Study	Type	# Pt s	Age (yrs)	Inclusion criteria	Exclusion criteria	W/D	Intervention
Balogh, 2005 (1)	RCT	56	40-79	-Low back pain for at least 12 months -Subjects have never used this specific mineral water before -Pts have not undergone balneotherapy in the past	Malignant HTN, heart failure, febrile conditions, infectious diseases, steroid therapy during pre-trial period	4	30 min bath in 36 degree Celsius reduced sulphurous mineral water on 15

				year -Lumbar pain was the principal complain of the participants -No other modality of physical treatment was used during course of study			consecutive days
Tenfer, 2012 (2)	RCT	60	40-79	-Ambulatory pts with low back pain not complicated by severely restricted mobility -non-specific low back pain for at least 12 weeks with tenderness of paravertebral muscles and limitation of motion of the lumbar spine -Lack of systemic or topical treatment with steroids, physical or balneotherapy within 2 months of the study	-Acute low back pain, organic neurological deficit associated with lumbar pain, suspected vertebral compression, history of spine surgery, CI to balneotherapy	20	15, 30 min balneotherapy sessions using thermal-mineral water at 31 degrees celius over 3 weeks; 5 days/week
Kesiktas, 2012 (3)	RCT	60	45-65	-Mechanic-character lumbar and leg pain for more than 3 months	-previous lumbar surgery, progressive neurologic loss, pregnancy, CI to Balneotherapy, patients exposed to balneotherapy or physical therapy in the past year	10	10, 30 minute sessions of balneotherapy with exercise program

OUTCOMES MEASURED

The outcomes measured were patient oriented evidence that matters (POEMs). In each RCT that was evaluated, a variety of subjective tools were utilized to assess participant’s experience. Tenfer (2012) measured the severity of the lower back pain using the visual analog scale (VAS) for lumbar pain, (zero point of the scale = no pain, endpoint = intolerable pain)

which was completed by the participant at baseline, after treatment and at the follow up evaluation. This study also looked at the participant consumption of analgesic and NSAID that was required, measured in number of tablets needed per week. The third and final measurement that was included in this review for this study was the Oswestry low back pain disability questionnaire (OSWDQ), that was completed by the subjects at baseline, post treatment and at the follow up period. The next study, Kesiktas (2012) also measured outcomes using the VAS, analgesic dose required, and the OSWDQ. The OSWDQ included a form complete with ten questions asking subjects to respond on a scale of 0-5 regarding their level of disability experienced due to their low back pain. The scores were then converted to percentages, with the greater percentages correlating to an increased disability index. Finally, Balogh (2005) measured outcomes of the trial using VAS, and analgesic dose required to relieve pain at baseline, post-treatment and during the follow up period.

RESULTS

The three single blind RCT follow up studies all compared treatment with balneotherapy to control groups that received tap water or tap water combined with physical therapy. All treatment groups in the trials received either 10 or 15 total balneotherapy sessions in varied treatment schedules. Safety was ensured in each trial with a physician that oversaw the balneotherapy sessions, recorded participant's vital signs and monitored for any potential adverse reactions.^{1,2,3}

Please note that the data from all three single blind RCT included in this review contained continuous data that could not be converted to dichotomous data. Without dichotomous data, it was not possible to calculate risk reduction(RRR), absolute risk reduction (ARR), numbers needed to treat (NNT) or numbers needed to harm(NNH). All participants in the

three RCT included, consented to participate in their studies and were made aware of their freedom to withdraw from the study if necessary. Balogh and Kesiktas had a withdraw rate that was less than 20%, and Tenfer had a withdraw rate of 30%.^{1,2,3}

The RCT conducted by Balogh in 2005 compared the use of reduced sulphurous mineral water on 30 patients who were assigned to the treatment group while the 30 participants in the control group were treated with modified tap water. Balneotherapy was delivered in 30 minute sessions on 15 consecutive days and participant condition was evaluated at baseline, at the end of the 15 day balneotherapy sessions and again 3 months post treatment.¹

Balogh included many different parameters to evaluate the outcomes of this study, however, for the purpose of this review the outcome measures analyzed were VAS of lumbar pain and analgesic dose required. Both the treatment and control group for this study showed a statistically significant reduction in pain intensity measured by the VAS with a significant p-value of <0.01. However, the participants who received balneotherapy, showed reduction in pain intensity that continued after treatment through the 3-month follow up period, where the control group VAS measurements returned almost to baseline at the 3-month follow up.¹ The mean analgesic dose requirement at post-treatment showed a greater change from baseline in the treatment group, compared to the control; (0.56 to 0.30 and 0.17 to 0.16, respectively) however neither group was considered statistically significant. Table 2 below summarizes the results of the study conducted by Balogh.

Table 2: Balogh-Outcomes measured at baseline and posttreatment, mean (SD)

	Control	Control	Balneotherapy	Balneotherapy
	Baseline	Post-treatment	Baseline	Post-treatment

VAS	4.67 (2.04)	2.43 (1.87)*	5.21 (1.8781)	2.34 (1.8570)*
Analgesic dose	0.17 (0.57)	0.16 (0.00)	0.56(1.3841)	0.30 (0.8864)

***Statistically significant, P-value <0.01**

The second study included in this review conducted by Tenfer (2012), included 60 adults aged 40-79 years old with chronic low back pain. 30 of the participants who were randomly assigned to the treatment group were exposed to thermal- mineral water for 30 minutes at a time 5 days a week for 3 weeks. The mineral water contained in this study contained an extremely high mineral content, characterized by sodium hydrogen carbonate, chloride, lithium, and bromide. The 30 participants assigned to the control group were exposed to temperature-controlled tap water for the same amount of time. Tenfer includes many parameters to evaluate outcomes of the study however for the purpose of this review, analysis of the results will focus on VAS, analgesic dose requirement and OSWDQ. Table 3 below displays the outcomes of these three measurement parameters that were recorded at baseline and again at week 6 of the trial. There were statistically significant results found with all three parameters for the balneotherapy group, where none of the parameters for the control group showed statistically significant reduction. VAS in the balneotherapy group decreased from 34.83 at baseline to 19.8 at week 6, making this outcome statistically significant with a p-value of <0.01.² The analgesic dose required for the treatment group showed a statistically significant reduction at week 6 (5.83) and continued reducing in the dose required by these subjects at week 13 (3.73).² Below, Table 3 summarizes the outcomes that were measured from the parameters included from Tenfer (2012).

Table 3: Tenfer- Outcomes measured at baseline and at week 6. Mean (SD)

	Control	Control	Balneotherapy	Balneotherapy
	Baseline	Week 6	Baseline	Week 6

VAS	40.37 (24.3)	43.67(23.7)	34.83 (27.6)	19.83 (21.8)*
Analgesic dose	4.74 (5.9)	4.48 (5.6)	5.83(6.9)	4.10(6.2)*
Oswestry's index	40.43 (15.2)	41.69 (15.9)	39.51 (18.0)	28.38 (17.80)*

***Statistically significant:**

p-value (VAS and OSWDQ) <0.01, and p-value (analgesic dose) <0.05

The third and final study included in this systematic review, was a single blind RCT follow up study conducted by Kesiktas (2012). This study involved 60 adults with chronic degenerative low back pain, who were selected and randomly assigned to one of two groups. The control group (group 1) participated in physical therapy modalities that included transcutaneous electric nerve stimulation (TENS), ultrasound, infrared radiation and exercise as an outpatient at a physical medicine and rehab hospital. The treatment group (group 2), was administered ten 30-minute sessions of balneotherapy in thermal mineral that was mainly characterized by calcium bicarbonate and sodium chloride.³ Similarly to the other studies in this review, this study evaluated the results by utilizing a variety of outcome measurements but for the purpose of this review, the parameters that will be analyzed are VAS at rest, analgesic dose requirement and OSWDQ. For the group receiving balneotherapy, statistical significant changes were observed for all three parameters and for the control group, statistical significance was measured in only VAS and OSWDQ.³ Although there were statistically significant differences in the control group, the change in mean from baseline was larger for the balneotherapy groups in both VAS and ODI. VAS in the control group at baseline was 29.63 and 14.81 at 3 months post treatment compared to the even greater change from baseline observed in the balneotherapy group from

31.30 at baseline to 8.82 at the 3 month measurement.³ Table 4 summarizes the results that were measured the RCT conducted by Kesiktas (2012).

Table 4: Kesiktas- Outcomes measured at baseline and at 3 month follow up, Mean (SD)

	Control (group1)	Control	Balneotherapy (group 2)	Balneotherapy
	Baseline	3 month F/U	Baseline	3 month F/U
VAS (rest)	29.63 (19.06)	14.81(20.45)*	31.30 (18.17)	8.82 (10.45)*
Analgesic dose	1.45 (0.9)	1.01(0.75)	1.47(1)	0.35(0.75)*
Oswestry's index	45 (15)	33 (16) *	46 (17.0)	31 (16)*

* Statistically significant results, P-value <0.05

DISCUSSION

This systematic review gathered results from three separate single blind RCTs, that reported statistically significant reduction of chronic low back pain in those treated with balneotherapy. Each of the articles selected healthy adults with chronic lumbar back pain and measured the effects of balneotherapy using many parameters; both subjective and objective. After review of these three studies, evidence shows that treatment with balneotherapy can reduce non-specific chronic low back pain.^{1,2,3}

Although the research done with this systematic review may show promising results of reducing low back pain, barriers to obtaining this treatment may exist in the real world. Natural mineral springs and medical spas originally thrived internationally but have only relatively recently increased in popularity in the United States. Consequently the availability of treatment

with balneotherapy may not meet potential demands.⁶ In addition to obstacles in gaining access to a facility that performs balneotherapy, there may also be some shortcomings in insurance coverage for the treatment because balneotherapy may be considered an alternative to traditional treatment modalities.⁶ While no black-box warnings exist for balneotherapy, there are some universal contraindications for use of the therapy.⁶ Certain populations of patients may be excluded from participating in treatment due to health risks including those with poorly controlled hypertension, congestive heart failure and respiratory insufficiency.^{1,2,3} Together those included above are the most significant potential obstacles in the accessibility of balneotherapy as treatment for low back pain.

In addition to considering barriers of a patient obtaining balneotherapy, this systematic review also evaluated the limitations of the three studies included. The number of subjects included in the RCTs was relatively small, averaging 50 participants. All three studies had participants that were lost to follow up and one study conducted by Tenfer had greater than 20% lost to follow up.² In addition, all three studies were only single blind and also had no way of controlling any additional treatment modalities that the participants may have engaged in outside of the trial. Another limitation that was considered is that the specific mineral content of the water used on the treatment groups in each trial, differed, which could complicate the results analysis.

CONCLUSION

Balneotherapy is considered effective for reducing non-specific chronic low back pain in adults. The three single blind follow up RCT that were considered in this review provide statistically significant results that support a decrease in low back pain and in turn, the level of disability the participants had to face from their painful condition. This research may not have

revealed the new “gold standard treatment” just yet, but for a patient suffering from chronic low back pain, any reduction in their suffering is considered a gain. Balneotherapy, as an entity of spa therapy, harnesses the potential anti-inflammatory and analgesic effects of mineral cation and anion absorption, and the physical properties of hydrotherapy to improve musculoskeletal pain.² The trials that were included in this review evaluated balneotherapy as a single treatment modality for its participants yet in the real world balneotherapy can serve as an adjunct to existing treatment modalities to further reduce back pain.

Although these studies are promising for the future of balneotherapy, more research needs to be completed to obtain information regarding specifics of successful treatment. Future studies may work to determine the ideal length, frequency and mineral composition of balneotherapy. For example, future study may compare mineral water with different dominating cations and anions, to demonstrate which showed the greatest reduction in low back pain. Research in the field of balneotherapy will surely continue as chronic low back pain maintains great clinical importance in the future of medicine.

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