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Effect of revulsive compress on low back pain: a randomized controlled trial

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Naturopathic medicine is a non-invasive and evidence-based system of medicine imparting treatments using natural modalities.This study was conducted to determine the effect of revulsive compress in improving pain, disability and spinal flexibility in patients with low back pain. A total of sixty subjects were recruited after fulfilling the inclusion and exclusion criteria. They were randomly allocated to the case group which received revulsive compress for ten days and the control group, without intervention, put on wait-list. Every subject was assessed for pain, disability and spinal flexibility at baseline and following 10 days. The data were analyzed for the normal distribution using the Kolmogorov Smirnov test. Parametric tests, t-test and paired t-test were applied for sit and reach test as the data measured was normally distributed. Non-parametric tests, ie., Mann-Whitney Test and Wilcoxon signed-rank tests were used for VAS and ODI as the data measured with these were non-normally distributed.There was a significant improvement in the sit and reach test ($p \leq 0.004$), VAS ($p \leq 0.0001$) and ODI ($p \leq 0.0001$) in the case group with respect to the control group. The study result suggests that the revulsive compress group showed significance for VAS Score, ODI, & sit and reach test with respect to the control group. Hence, revulsive compress may be an effective hydrotherapeutic treatment for a reduction in pain and disability and in improving the flexibility in low back pain patients.

Keywords: Contrast therapy, Hydrotherapy, Low back pain, Naturopathy, ODI, VAS

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Low back pain (LBP) is an extremely common musculoskeletal problem affecting all age groups at some point in life. It is a symptom that may occur as a result of various known or unknown abnormalities. The social burden associated with low back pain makes it a major public health concern[1]. It is characterized by pain, muscle tension or stiffness localized anywhere between the costal margin and inferior gluteal folds, presented with or without leg pain, i.e., sciatica[2]. LBP can be either specific or nonspecific. There is always an underlying pathophysiological mechanism for specific LBP whereas non-specific low back pain is without a clear cause. Specific LBP is rarely identified as for almost all patients presenting with LBP, the specific nociceptive source cannot be identified and therefore, most low back pain is non-specific. It is classified by the duration of pain into acute, subacute and chronic low back pain[2]. Acute LBP is when the duration of an episode of LBP persists for less than 6 weeks, subacute LBP is when it persists more than 6 weeks, but less than 3 months, chronic LBP is when pain persists for more than 3 months[2]. LBP was initially considered to be a major health problem in developed countries, but recent studies show an increased prevalence in developing countries too[3]. The annual world wide low back pain incidence is estimated to be 15% and point prevalence to be 30%[4]. Most adults suffer low back pain at some point, prevalence peaking in mid-life. LBP associated with activity limitation increases with age. It affects men and women equally, although some studies show women to be more affected by low back pain than men[1,5]. The mean prevalence in high-income countries is greater than in middle-income and low-income countries.Sedentary behavior and lifestyle factors such as smoking, obesity and physical inactivity correlate with poorer general health, thus associated with the occurance of LBP[6]. CAM is a broad domain of healing resources that encompasses all health systems and modalities including Traditional Chinese medicine,

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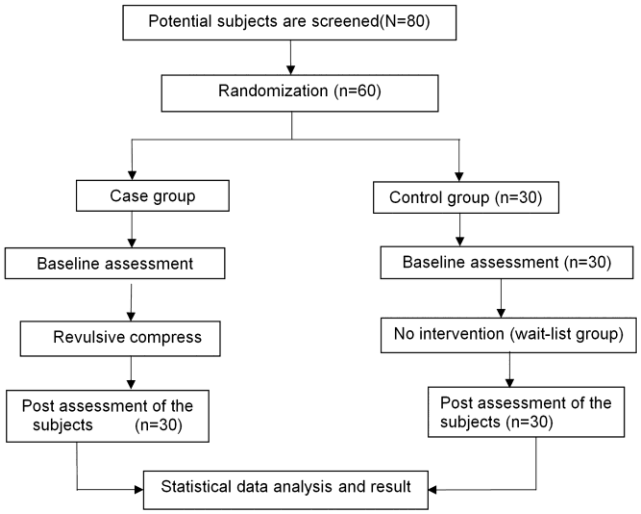
Ayurveda, Homeopathy, Naturopathy and Yoga[7]. Naturopathy is a drugless system with a holistic approach, which believes in the body's innate capacity to heal itself[8]. Hydrotherapy is one of the main treatment modalities of naturopathy that uses water, externally or internally, in any of its form (water, ice, steam) for health promotion or treatment of various diseases at different temperatures, pressures, duration and site[9]. Revulsive compress is one of the hydrotherapy treatments which involves the alternate application of hot (98-104°F) / (36-40°C) immediately followed by cold (55-65°F)/ (12-18°C) which helps to improve the blood circulation, ease inflammation, reduce edema and strengthen the connective tissue[10]. Revulsive compress is a treatment of choice in the management of low back pain in naturopathy. Hence, the current study was aimed to evaluate the efficacy of revulsive compress on low back pain.

Methodology

Sixty subjects aged between 19 to 60 years, fulfilling the diagnostic criteria for low back pain were recruited from S.D.M College of Naturopathy and Yogic sciences outpatient department and students of SDM residential hostel, Shantivana, Ujire. The wide range age group was included because low back pain affects all age groups[11,12]. They were randomly assigned to the case and control group using the chit-pull method of randomization. Signed informed consent was obtained from all the participants after an appraisal about the study protocol and Institutional Ethical Committee approval was obtained with the registration number EC-198, as all tests were essentially non-invasive. There were equal number of subjects (30 each) in the case group (revulsive compress) and control group (wait-list). Sample size was not calculated a-priori as we had convenient sampling. However a post-hoc analysis determined the power to be 0.99, demonstrating adequacy of the sample size. Revulsive compress was administered to the subjects belonging to the case group for 20 min, in which a hot fomentation bag was applied over the lower back for 4 min followed by a cold application for 1 min. Subjects were assessed using the selected outcome variables at the baseline as pre-assessment on the first day and post-assessment after 10 days of intervention.



Trial Profile

Materials and Methods

The visual analog scale (VAS) was used to assess the severity of pain. The subjects were asked to rate the severity of low back pain by visual assessment technique with a scale of 0-10 cm[13].

Low back pain disability was assessed using the Oswestry Disability Index (ODI) considered being the gold standard for assessing the disability level of back pain. The Oswestry disability index is the main condition-specific outcome measures and therefore used in the management of spinal disorders[14].

The sit-and-reach test was used to measure hamstring and lower back flexibility in the subjects. The subject was asked to sit on the floor with legs extended towards the sit and reach apparatus touching it, followed by bending forward to their maximum capacity pushing the indicator with his fingers keeping the elbows straight. The distance covered was then measured in centimeters[15].

The data were analyzed for the normal distribution by the Kolmogorov Smirnov test. Parametric tests were applied for sit and reach tests and hip goniometry as the data measured with these were normally distributed. A t-test was used for between-group analysis and a paired t-test was used for within-group analysis. Non-parametric tests were used for VAS and ODI because the data measured with these were not normally distributed. Mann-Whitney test was applied for between-group analysis and Wilcoxon signed-rank test was applied for within-group analysis.

Results

Between-group analysis for sit and reach test pre and post-intervention with respect to case and control

group was done using a t-test. The Pre-intervention sit and reach test between case and control group showed no significant difference ($p \leq 0.14$) indicating an equal baseline. Post-intervention sit and reach tests between case and control groups showed a significant difference ($p \leq 0.004$) indicating a significant improvement in spinal flexibility in the case group when compared to the control group.

Within-group sit and reach test pre and post-intervention analysis was done using a Paired sample t-test, showed a significant difference ($p \leq 0.0001$) in the case group suggesting that there was a significant improvement in spinal flexibility. The control group also showed an improvement ($p \leq 0.039$).

Between-group analysis for VAS pre and post-intervention with respect to case and control group was done using Mann-Whitney Test. Pre-intervention VAS between case and control group showed no significant difference ($p \leq 0.129$) indicating a model with an equal baseline. Post-intervention VAS between case and control group showed a significant difference, favoring the case group ($p \leq 0.0001$).

Within-group VAS pre and post-intervention analysis was done using the Wilcoxon signed-rank test, which showed a significant difference ($p \leq 0.0001$) in the case group suggesting that there was a significant improvement in pain. The Control group showed no difference ($p \leq 0.366$).

Between-group analysis for ODI pre and post-intervention with respect to case and control group was done using Mann-Whitney Test. Pre-intervention ODI between case and control group showed no significant difference ($p \leq 0.865$) indicating an equal baseline. Post-intervention ODI between case and control groups showed a significant difference ($p \leq 0.0001$).

Within-group ODI pre and post-intervention analysis was done using the Wilcoxon signed-rank test, which showed a significant difference ($p \leq 0.0001$) in the case group suggesting that there was a significant improvement in disability. The Control group showed no difference ($p \leq 0.332$).

Discussion

The significant improvement in low back pain in the case group can be due to the effect of both hot and cold applications that are shown to have an equal effect on relieving acute and chronic low back pain[16]. The primary effect of the superficial cold application is analgesia and associated reduction of reflex muscle spasm[17]. A local anesthetic effect known as cold-induced neuropraxia happens when the nerves are cooled, due to three mechanisms namely (i) by reducing the nerve conduction velocity (ii) by increasing pain threshold due to decreased activation threshold of tissue nociceptors and (iii) by increasing pain tolerance[18]. Pain control also happens at the spinal level through inhibition of pain transmission to higher centers via the gate control theory of pain transmission[19]. Similarly, the superficial heat reduces pain by causing vasodilatation, increasing blood flow to deep tissues, further reducing ischemia of the injured tissue and thus, resulting in reduced activity of pain receptors[17,20].

The heat application is also shown to stimulate the cutaneous thermal receptors leading to the inhibition of pain transmission at the posterior horn of the spinal cord through the gate control mechanism. Superficial heat also induces muscle relaxation due to a reduction in transmission of impulses via type II muscle spindle afferents and gamma efferents and an increase in the transmission of impulses via type II fibers of the Golgi tendon organs. These, successively, results in reduced firing of the alpha motor neuron to the extrafusal muscle fiber, which leads to muscle relaxation[17]. Decreased pain also results in reduced muscle spasm that alleviate the pressure exerted by the muscles on blood vessels, lowering ischemia and improving blood flow[20]. Heat has been shown to accelerate both enzymatic and metabolic biochemical reactions, enhances oxygen uptake by the tissues and promotes tissue damage, recovery and healing.Thus heat and cold application together by the above-mentioned mechanisms contribute to pain reduction and disability.

Biochemical changes were not evaluated in the current study whereas some other studies on contrast water therapy application showed decreased blood lactate concentration, hastening blood lactate clearance improving muscle fatigue[21].

An increase in intramuscular tissue oxygenated hemoglobin (O_2Hb), Tissue oxygenation saturation index (TSI%) and total hemoglobin (tHb) was observed, indicating increased intramuscular perfusion and oxygenation after contrast water therapy. It has been shown to improve the tissue hemodynamics and oxygenation that are regarded as essential mechanisms of tissue repair in treating acute or chronic muscle damage and soreness associated

with low back pain. Significantly lower values of CK (Creatine Kinase) and (Mb) plasma concentrations were observed after contrast water therapy[22,23].

An alternate application of hot and cold produces a strong circulatory action without producing a thermic reaction[10]. Hot application is longer than the cold application, augmenting the effect of vasodilatation. This alternating vasodilatation and vasoconstriction of the peripheral blood vessels induces intracellular-intravascular fluid shift, thus altering the perfusion to the muscle resulting in an attenuated immune response and decreased myocellular damage[23]. This mechanism was recently established in a study on contrast bath and blood circulation using near-infrared spectroscopy[22]. These evidences further support the presumed mechanism of revulsive compress application in treating low back pain patients.

According to Fiscus *et al*.[24] the preferred ratio of heat application to cold application is 4:1, to produce fluctuation blood flow and significant physiological effects. The same was adopted in the present study.

Improvement in flexibility in the current study can be attributed to the effect of heat on the stretch that is mainly derived from the connective tissue structures in and around muscles. Flexibility is improved by an increase in tissue temperature, changing the biomechanical characteristics of collagen, improving connective tissue extensibility and thus the range of motion[25]. At 104, a transition in the microstructure of collagen, as a result of partial destabilization of intermolecular bonding, allows greater stretching, because of the relaxation of collagenous tissue[25-28]. Finally, the application of revulsive compress also lead to the cessation of the pain-spasm-pain cycle, inhibiting muscle spasm and pain perception, enhancing flexibility and range of motion[29].

As the intervention is simple, cost-effective, and economically accessible, it can be easily implemented in the management of low back pain.

Future research studies must include objective variables (EMG studies), a larger sample, and a follow-up duration to authenticate the reported benefits of this study.

Conclusion

The findings of the study suggest that revulsive compress as a hydrotherapeutic treatment may be effective in treating the patients with low back pain. The present study showed a significant reduction in VAS score and ODI scores indicating a reduction in pain and disability. An improvement in flexibility of the lower back was seen when assessed with sit and reach test, after 10 days of revulsive compress applied to the lower back. Since the intervention has fewer to no side effects and are economically accessible, it may be an effective treatment for low back pain.

Declaration

Signed informed consent was obtained from all the participants after an appraisal about the study protocol and Institutional Ethical Committee approval (EC-198) was obtained, as all tests were essentially non-invasive in nature.

Conflict of Interest

All the authors declare no conflict of interest.

Author's Contributions

Conceptualization and designing of the study: A M S & K J S; Original draft, Reviewing and Editing: A M S; Formal Analysis, Methodology and Interpretation of Data: A M S, K J S & S P; Final approval of the manuscript: A M S, K J S & S P.

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