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Original research article

A single blind randomised control trial to evaluate the effect of Mg supplementation in combination with conventional physiotherapy management in subject with chronic low back pain

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Abstract

Background: Low back pain is defined as any pain, muscle tension, or stiffness localized below the costal margin and above the inferior gluteal fold, pain may be radiated through the leg or not. Epidemiological studies have generally considered that risk factors for starting backache are interrelated in three dimensions: individual factors and lifestyle, physical or biomechanical factors, and psychosocial factors.

Method: Single blind randomised control trial used in this study with the sample size of 100 people, allocated in 2 group 50 in each group, Group A (Mg tansdermal patch) and group B serum is used.

Result- Magnesium with physiotherapy group shows significant improvement in comparison with serum group.

Discussion and Conclusion: Magnesium sulfate (MgSO4) is commonly used for the treatment of musculoskeletal problems as it has muscle relaxant and vasodilator properties that can have an analgesic effect. We found similar and other effect in different studies

Keywords: Low back Pain, Muscle

Introduction

Any discomfort, muscular strain, or stiffness that is localised below the costal border and above the inferior gluteal fold is referred to as low back pain, whether or not it radiates into the leg [1]. Alternatively, it is described as "the modern view that back pain is typically a chronic health condition with an unpredictable pattern of symptomatic episodes, remission, and recurrence." One of the main causes of low back pain's significant global social and economic cost is its fluctuating nature [2]. Chronic low back pain should be viewed as a serious public health issue since it is frequently the leading cause of long-term disability in middle age in many nations. Among people under 45, it ranks as the second most frequent reason for missed workdays and activity restrictions [3]. Magnesium (Mg) is frequently used as an adjunctive medication in the community by pain sufferers and healthy individuals to enhance their wellbeing and lessen stress [4]. Magnesium has also been identified as a cofactor for more than 300 enzymatic processes, where it is essential for the metabolism of adenosine triphosphate (ATP). Magnesium is necessary for the synthesis of protein, DNA, and RNA as well as for reproduction. Additionally, magnesium is necessary for the control of cardiac excitability, blood pressure, insulin metabolism, nerve conduction, vasomotor tone, and muscle contraction [5].

Back pain's cultural, societal, and political context can affect how it feels, how it makes you disabled, and how you utilise medical services. CLBP has a high incidence and recurrence rate, which places a significant social and financial burden on the patient, their family, and society. Finding an appropriate therapy for CLBP is so crucial yet extremely difficult. Transdermal Mg administration and standard physiotherapy care will be used in conjunction in the current trial to treat CLBP patients, extending the positive benefits on functional outcomes beyond what each intervention could achieve on its own.

Aim of the Study

To evaluate the effect of Mg supplementation in combination with conventional physiotherapy management on functional recovery in subjects with chronic low back pain.

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Objectives of the Study

1. To determine how functional recovery in individuals with persistent low back pain is affected by Mg supplementation in conjunction with traditional physiotherapy care.
2. To determine the effect of Mg supplementation in combination with conventional physiotherapy management on functional disability in subjects with chronic low back pain by using VAS score.
3. To determine the effect of Mg supplementation in combination with conventional physiotherapy management on pain in subjects with chronic low back pain by using serum mg level.

Methodology

The present study is single blind Randomised controlled trial. In which subjects with CLBP will be divided into two groups for the current study: Group A (Experimental) and Group B (Control). While Group B will get standard saline water based sprays on the afflicted region along with traditional physiotherapy care, Group A will receive the transdermal application of Mg oils. Subjects are don't know about treatment allocation in different groups.

Consent and ethical considerations

The purposed study was applied for ethical approval to conduct the research from Institutional Ethical Committee, Malwanchal University, Indore. A Written Consent was obtained from each subject who will be willing to participate in the study before the commencement of the study.

Study Population

The study population consisted of all adults with chronic low back pain, with age 18-50 years will be selected from the various hospitals, rehabilitation centers and communities of District Mumbai and its surrounding cities.

Sample Size

The Sample size of the study is calculated by using the power analysis and effect size of outcome measure from previous studies used in these study. The sample size for these study is 100 according to power analysis with included the 5% of drop out rate and participants will be randomly assigned into two groups (50 in each group).

Sampling method

For sampling we used simple random sampling methods. In which first we make sampling frame and after that we used computer based random sampling methods to allocate subjects in study and control group.

Inclusion criteria

- Both males and females with age ranging from 18 – 50 years.
- Patients having history of back pain for a period of minimum 12 weeks.

Exclusion criteria

- Participation in other pharmacological & rehabilitation studies during the study period
- Severe cardiovascular like Cardiac arrhythmias, non-controlled blood pressure & severe respiratory problems
- History of any spine surgery
- Pregnant women

Data Analysis

After gather all data we enter in Xl Sheet and for analysis we used SPSS version 16.0, Mean, SD, and Anova test used to found result

Result

In current study we found significant positive difference result in Group A (Magnesium with Physiotherapy) in comparison with Control group B (Serum with Physiotherapy).

Table 1: Age wise distribution of patients among Group A and Group B

	A		B		Total	
Age group (yrs)	**No.**	**%**	**No.**	**%**	**No.**	**%**
<31	15	30.00%	9	18.00%	24	24.00%
31-40	17	34.00%	28	56.00%	45	45.00%
41-50	18	36.00%	13	26.00%	31	31.00%
Total	50	100.00%	50	100.00%	100	100.00%

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Table-1 shows distribution of subjects according to age

Table 2: Gender wise Distribution of Patients Among Group A and Group B

	A		B		Total	
Gender	**No.**	**%**	**No.**	**%**	**No.**	**%**
Male	22	44.00%	21	42.00%	43	43.00%
Female	28	56.00%	29	58.00%	57	57.00%
Total	50	100.00%	50	100.00%	100	100.00%

Table 2 presents the number of males and females who participated in the study.

Table 3: Mean and SD of VAS at 0 days, 10 days and 20 days for Group A and Group B

VAS	Group A		Group B	
	Mean	**SD**	**Mean**	**SD**
0 day	6.24	1.29	6.32	1.45
10^{th} day	4.14	1.53	5.26	1.69
20^{th} day	2.18	1.56	4.32	2.00
MD (0 -10^{th}) days	2.10	1.53	1.06	1.20
MD (0 -20^{th}) days	4.06	1.79	2.00	1.47
MD (10 -20^{th}) days	1.96	1.24	0.94	1.27

Table 3 displays the comparison of VAS score and Mean Difference among Group A and Group B at three different intervals (0^{th} day, 10^{th} day & 20^{th} day). At 0^{th} day, 10^{th} day & 20^{th} day the mean is declining more rapidly in study group and control group.

Table 4: Comparison of Mean Value for VAS at 0 days, 10 days and 20 days (Anova Test)

VAS	ANOVA	
	'f' value	**P value**
0 day	0.845	0.436
10^{th} day	2.416	0.100
20^{th} day	1.783	0.179
MD (0 -10^{th}) days	0.996	0.377
MD (0 -20^{th}) days	0.790	0.460
MD (10 -20^{th}) days	0.021	0.979

Table-4 displays the comparison of VAS SCORE according ANOVA test show significant difference.

Table 5: Comparison of Mean Value for Serum Mg Level at 0 days, 10 days, 20 days and within Group A and Group B

Serum Mg Level	Group A		Group B	
	Mean	**SD**	**Mean**	**SD**
0 day	1.38	0.65	1.61	0.72
10th day	1.63	0.54	1.58	0.65
20th day	1.89	0.52	1.61	0.60

Table shows group A increase level of mg in 0, 10, 20 days and in group B it is almost constant all days.

Discussion

In current study we found much improvement in chronic low back pain in experimental group (use transdermal magnesium with physiotherapy) verses control group.

Similarly Yousef *et al.* found that the use of MgSO4 supplements during the postoperative period in patients with refractory chronic lower back pain reduced pain intensity and improved lumbar spine mobility [6].

Santosh D. A found Serum magnesium levels and muscle performance have been shown to be positively correlated for outcomes like grip strength and vertical jump [7].

While Lamontagne C, *et al.* not found any evidence supporting the use of magnesium supplementation in myofascial chronic back pain. However, there is a small body of evidence demonstrating the efficacy of magnesium in the prophylaxis of migraine and tension-type headaches, and in reducing pain scores in patients with complex regional pain syndrome (CRPS) type 1 [8].

Refahee *et al.* 2022, did a study to evaluate the clinical efficacy of MgSo4 injections in the treatment of masseter muscles with TrPs when compared to saline injections. MgSo4 has been recommended for the treatment of myofascial TrPs due to its muscle relaxant and vasodilator properties that can have a pain-relieving effect [9].

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Gender also contributes to magnesium status as estrogen enhances magnesium utilization, favoring its uptake by soft and hard tissues. Young women have better magnesium retention than young men, and as a result of this, their circulating magnesium levels are lower, particularly at the time of ovulation or during oral contraceptive use, when estrogen levels are highest. Consequently, samples taken in a mixed gender population or at time points that do not take this into account could further confound human magnesium studies [10].

In Group A, the age wise distribution of the participants were done at three categories, <31, 31-40 & 41-50 total 15,17 & 18 patients were included respectively in which 22 were males and 28 females. While in Group B, the age <31, 31-40 & 41-50 in which 9,28 & 13 patients were included respectively in which 21 were males and 29 females.

The current study used the VAS scale to estimate pain intensity at each study interval, and significantly lower values were observed in patients receiving MgSo4 injections at all follow-up intervals when compared to patients receiving saline injections ($p< 0.05$). This could likely be attributed to the increased vasodilation provided by the former in several vascular beds, resulting in greater blood flow to the trigger point and removal of irritating substances that cause pain. Additionally, it also eliminates muscle tension and excessive tenderness by competing with calcium at the motor end plate and reducing acetylcholine discharge. This, in turn, leads to reduction of pain intensity at the site of injection, and these findings are in harmony with those of Ibrahim *et al.,* 2021 who also reported observing a palliative effect following iontophoresis with MgSO4 in healthy adult volunteers [11]. Furthermore, Sane *et al.,* 2020 studied the effect of local injection of ropivacaine and bupivacaine injection with magnesium sulfate on postoperative pain in vertebral laminectomy surgery and concluded that local anesthesia combined with magnesium sulfate provided greater postoperative analgesia [12].

The Serum Mg level was significant improved in Group A as comparatively to Group B, Similarly Watkins & Josling, 2010 also find significant improvement in serum Mg levels, After transdermal applications of mg for 12 weeks all patients except one had a significant increase in cellular magnesium ranging from 2% to 262% [13].

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