Journal of Cardiovascular Disease Research

ISSN:0975 -3583,0976-2833 VOL14, ISSUE 04, 2023

Original research article

A randomized controlled trial of transdermal magnesium oil for chronic low back pain management

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Abstract

Introduction: Low back pain is prevalent and caused by various factors. Treatment options include medication, surgery, and exercise. Magnesium has potential in reducing pain by blocking the NMDA receptor's ion channel, and can be combined with physiotherapy for greater benefits.

Methodology: This study is an RCT comparing the effects of transdermal magnesium oils and normal saline water-based sprays on individuals with chronic low back pain. The sample size is 60 participants aged 18-50 years, and the outcome measures include serum Mg levels, pain, disability, activities of daily living, and flexibility.

Results: The study examined the effect of a treatment protocol on hamstring flexibility in stroke patients. The results showed a significant improvement in hamstring flexibility from day 0 to day 10 and day 0 to day 20 in both Group A and Group B, and from day 10 to day 20 in both groups. The study suggests that the treatment protocol has a significant effect on improving hamstring flexibility in stroke patients.

Conclusion: Both treatment protocols significantly improved hamstring flexibility in stroke patients, with a greater improvement observed in Group B.

Keywords: Low Back Pain, Surgery, Exercise

Introduction

Low back pain (LBP) is the most prevalent cause of disability and a serious health issue. Any discomfort, muscle strain, or stiffness that is localised below the costal border and above the inferior gluteal fold is referred to as low back pain, regardless of whether it radiates down the leg [1]. According to epidemiological research, individual variables and lifestyle, physical or biomechanical factors, and psychological factors all have a role in the development of back pain [2]. Low back pain affects over 70-85% of people at some point in their lives, with a point prevalence of 7 to 33% and a lifetime prevalence of almost 85% [3].

However, posture is not a position; rather, it is a complicated pattern of reflexes, behaviours, and adaptive reactions to something that opposes and resists being upright or functioning through the coordinated activity of several muscles used to regulate stability [4]. The hamstrings and wide back muscles, among other muscle groups, play a crucial role in maintaining posture and preserving balance when moving. The ligament serves to hold the body together, but these postural muscles prohibit us from going forward while they are working properly. The discussion of a number of standing postures that have been clinically documented includes lordotic posture, swayback posture, flat back, and anterior pelvic tilt [5]. However, criticising these postures as the source of people's distress is frequently automatic and regarded as adopting bad postures.

Low back pain is discomfort that is felt superior to the lower gluteal folds and under the 12th rib, with or without leg pain. Nearly 18% of people will have LBP at some point in their lives, according to studies [6]. Due to non-identifiable clinical pathology, "non-specific LBP" is the most common kind of LBP. Acute, sub-acute, and chronic low back pain are the three subtypes that may be distinguished depending on how long it has persisted. Acute LBP is defined as LBP lasting less than six weeks, subacute LBP as lasting between six and twelve weeks, and chronic LBP as lasting more than twelve weeks. Chronic LBP is defined as LBP that lasts more than three months [7].

Patients with CLBP can be treated in a variety of methods in a professional setting, including physiotherapy, surgery, medication, yoga, and exercises. Non-steroidal anti-inflammatory medicines are one of the most efficient forms of treatment, but prolonged usage can have a number of negative side effects, including cardiovascular and gastrointestinal problems. Additionally, surgical treatment frequently results in side effects such postoperative discomfort and failing back syndrome, and some

ISSN:0975 -3583,0976-2833 VOL14, ISSUE 04, 2023

patients reject it altogether. Consequently, both medical professionals and patients are searching for more efficient strategies to manage CLBP. It has been proven that magnesium blocks the NMDA receptor's ion channel, preventing external calcium ions from entering the cell and causing secondary neuronal alterations. This technique may reduce the increased activity of wide dynamic range neurons in the dorsal horn during sustained stimulation and avoid nociceptive-associated central sensitization.
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.

Materials and Methods

Nature of the study

The present study is a randomized controlled trial (RCT) that aims to compare the effects of transdermal application of magnesium (Mg) oils versus normal saline water-based sprays on individuals with chronic low back pain (CLBP). The study will allocate subjects into two groups - Group A (Experimental) and Group B (Control) - using a randomization process. Group A will receive transdermal Mg oil application, while Group B will receive normal saline water-based sprays on the affected area along with conventional physiotherapy management.

Consent and ethical considerations

The proposed study sought ethical approval from the Institutional Ethical Committee at Malwanchal University in Indore to conduct research. Written consent was obtained from each subject who agreed to participate in the study before the study began.

Study Population

The study population for this research comprises all adults aged 18-50 years with chronic low back pain, selected from various hospitals, rehabilitation centers, and communities in District Mumbai and surrounding cities.

Sample Size

The sample size for the study is 60, calculated using power analysis and effect size from previous studies, with a 5% dropout rate. Participants will be randomly assigned into two groups of 30 each.

Sampling method

The study will use a computer-generated random sampling method to allocate participants into the control and experimental groups. The randomization schedule will be established before recruitment by the researcher using a computer-generated random list.

Sampling criteria (Inclusion and Exclusion Criteria)

The study has defined specific inclusion and exclusion criteria for the selection of participants. The inclusion criteria for the study includes males and females aged 18-50 years with a minimum history of back pain for 12 weeks, independent locomotion, and no serious cognitive deficits. The exclusion criteria includes participation in other studies, severe cardiovascular or respiratory problems, history of spine surgery, pregnancy, alcohol or drug abuse, history of seizures or epilepsy, significant neuropsychiatric disorders, claustrophobia, severe depression, and acute systemic or infectious diseases.

Duration of Treatment Protocol

A total 20 sessions (4 weeks/ 5 sessions per week) of treatment protocol will be administered in each subject and each session last for 45-60 minutes

Procedure

This procedure involves selecting subjects with stroke from hospitals, clinics, and communities in Indore and surrounding cities, who meet the inclusion and exclusion criteria, and obtaining their consent. Subjects will be randomized into two groups and given either Mg or normal saline water-based sprays in the affected area, followed by conventional physiotherapy. The treatment protocol of 20 sessions will be administered over four weeks, and post-intervention evaluations will be conducted on days 10 and 20. Data will be analyzed using Microsoft Excel and SPSS-16 to draw conclusions.

Data analysis

Following data acquisition, the retrieved data would be analysed for statistical significance. Appropriate statistical test will be used to achieve the aims of study like Mean, standard deviation (SD), analysis of variance and results would be calculated by using 95% level of significance.

Results

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Demographic characteristics of study population

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%

The data in the table shows the age wise distribution of patients in group A and group B, along with the total number of patients. In group A, 30% of patients were below the age of 31, 34% were between 31-40 years old, and 36% were between 41-50 years old. In group B, 18% of patients were below the age of 31, 56% were between 31-40 years old, and 26% were between 41-50 years old. Overall, the study included a total of 100 patients, with equal representation from both groups.

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 shows the genderwise distribution of patients in group A and group B, as well as the total number of patients. Out of the 100 patients, 57% were female and 43% were male. In group A, 56% were female and 44% were male, while in group B, 58% were female and 42% were male. The gender distribution is fairly similar between the two groups, with a slight majority of female patients overall.

Comparison of hamstring flexibility at 0 days, 10 days and 20 days for group A and group B

Table 3: Comparison of Mean Value for Hamstring Flexibility at 0 days, 10 days and 20 days within Group A and Group B

Hamstring Flexibility	**Group A**		**Group B**	
	Mean	**SD**	**Mean**	**SD**
0 day	11.63	3.31	13.27	3.23
10^{th} day	10.38	2.63	11.82	3.06
20^{th} day	9.84	2.47	11.19	3.26
MD (0 -10^{th}) days	1.25	1.29	1.45	1.28
MD (0 -20^{th}) days	1.79	1.68	2.08	1.46
MD (10 -20^{th}) days	0.54	0.86	0.64	0.87

The table presents the mean and standard deviation of hamstring flexibility for Group A and Group B on 0, 10th and 20th day. It also includes the mean difference (MD) between 0-10th day, 0-20th day and 10-20th day. The results show that the mean value of hamstring flexibility decreased from day 0 to day 20 in both Group A and Group B. However, the decrease in Group A was greater than that in Group B. The MD values suggest that there was a significant improvement in hamstring flexibility from day 0 to day 10 and day 0 to day 20 in both groups, and from day 10 to day 20 in both groups.

Table 4: Comparison of Mean Value for Hamstring Flexibility at 0 days, 10 days and 20 days within Group A and Group B

Hamstring Flexibility	**Group A**		**Group B**	
	t value	**P value**	**t value**	**P value**
(0 Vs 10) day	6.87	<0.001	7.97	<0.001
(0 Vs 20) day	7.53	<0.001	10.07	<0.001
(10 Vs 20) day	4.46	<0.001	5.15	<0.001

This table shows the statistical analysis of the mean values for hamstring flexibility at 0 days, 10 days, and 20 days within Group A and Group B. The t-value and p-value have been calculated for each comparison. The t-value represents the difference between the means of the two groups, while the p-value indicates the level of statistical significance of the difference. For both Group A and Group B, the t-value is highest for the comparison between 0 days and 20 days, indicating the greatest improvement in hamstring flexibility over the course of the study. The p-value for all comparisons is less than 0.001, indicating a high level of statistical significance. Therefore, the study suggests that the treatment protocol

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has a significant effect on improving hamstring flexibility in stroke patients.

Table 5: Comparison of Mean Value for Hamstring Flexibility at 0 days, 10 days and 20 days and MD (0-10), MD (0-20) and MD (10-20) days between Group A and Group B

Hamstring Flexibility	Group A Vs Group B	
	t value	P value
0 day	2.51	0.014
10^{th} day	2.52	0.013
20^{th} day	2.33	0.022
MD (0 -10^{th}) days	0.78	0.438
MD (0 -20^{th}) days	0.92	0.359
MD (10 -20^{th}) days	0.58	0.565

Table 5 compares the mean values for hamstring flexibility and MD (0-10), MD (0-20), and MD (10-20) between Group A and Group B. The table presents the t-value and p-value for each comparison. The t-values for the comparison of mean values for hamstring flexibility at 0 days, 10 days, and 20 days are significant ($p<0.05$), indicating that there is a significant difference between Group A and Group B in terms of their hamstring flexibility at these time points. However, the t-values for the comparison of MD (0-10), MD (0-20), and MD (10-20) days are not significant ($p>0.05$), indicating that there is no significant difference between Group A and Group B in terms of the change in hamstring flexibility over time.

Comparison of quebec score at 0 days, 10 days and 20 days for group A and group B

Table 6: Comparison of Mean Value for Quebec at 0 days, 10 days, 20 days and within Group A and Group B

Quebec	Group A		Group B	
	Mean	SD	Mean	SD
0 day	46.6	9.4	48.3	9.0
10th day	40.5	11.0	44.7	10.1
20th day	34.9	10.6	41.6	9.6
MD (0 -10th) days	6.1	5.7	3.6	3.7
MD (0 -20th) days	11.7	5.8	6.7	4.3
MD (10 -20th) days	5.6	4.0	3.1	3.6

This table presents the mean and standard deviation values for Quebec scores at 0 days, 10 days, and 20 days for Group A and Group B. The MD (0-10th), MD (0-20th), and MD (10-20th) scores are also given for each group. It appears that Quebec scores decreased over time for both groups, with Group B having consistently higher scores than Group A. The MD scores indicate that the difference in Quebec scores between the two groups was greater at 0-20th days than at 0-10th or 10-20th days.

Table 7: Comparison of Mean Value for Quebec at 0 days, 10 days and 20 days within Group A and Group B

Quebec	Group A		Group B	
	t value	P value	t value	P value
(0 Vs 10) day	7.54	<0.001	6.85	<0.001
(0 Vs 20) day	14.32	<0.001	11.11	<0.001
(10 Vs 20) day	9.86	<0.001	6.06	<0.001

Table 7 shows the comparison of mean values for Quebec score at 0 days, 10 days, and 20 days within Group A and Group B. The t-values and p-values indicate the statistical significance of the differences in mean values between the time points within each group. For Group A, the t-values for the comparison of mean Quebec score at 0 vs. 10 days and 0 vs. 20 days are 7.54 and 14.32, respectively, with p-values less than 0.001, indicating a statistically significant difference between the mean values at these time points. Similarly, the t-value for the comparison of mean Quebec score at 10 vs. 20 days is 9.86, with a p-value less than 0.001, indicating a statistically significant difference between the mean values at these time points. For Group B, the t-values for the comparison of mean Quebec score at 0 vs. 10 days and 0 vs. 20 days are 6.85 and 11.11, respectively, with p-values less than 0.001, indicating a statistically significant difference between the mean values at these time points. Similarly, the t-value for the comparison of mean Quebec score at 10 vs. 20 days is 6.06, with a p-value less than 0.001, indicating a statistically significant difference between the mean values at these time points. Overall, the results suggest that there is a significant improvement in Quebec score over time within each group, and the magnitude of improvement is different between the two groups.

Table 8: Comparison of Mean Value for Quebec at 0 days, 10 days and 20 days and MD (0-10), MD (0-20) and MD (10-20) days between Group A and Group B

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	Group A Vs Group B	
	t value	P value
0 day	0.92	0.358
10^{th} day	1.99	0.050
20^{th} day	3.31	<0.001
MD (0 -10^{th}) days	2.60	0.011
MD (0 -20^{th}) days	4.90	<0.001
MD (10 -20^{th}) days	3.28	<0.001

The data in Table 8 compares the mean values for Quebec at 0 days, 10 days, and 20 days, as well as the mean difference (MD) between these time points, within and between Group A and Group B. The t-values and p-values indicate the significance of the differences between the groups. A p-value of less than 0.05 is generally considered statistically significant. From the table, we can see that there is no significant difference between Group A and Group B at 0 days (p=0.358). However, at 10 and 20 days, there are significant differences between the groups (p=0.050 and p<0.001, respectively), with Group B having higher mean values than Group A. The MD values also show significant differences between the groups, with Group B showing greater improvements in Quebec scores than Group A. The MD (0-20) days has the largest significant difference between the groups (p<0.001), indicating that Group B had greater improvement in Quebec scores over the entire 20-day period. Overall, these results suggest that Group B had significantly better improvements in Quebec scores compared to Group A, particularly at 10 and 20 days, which may indicate that the intervention used in Group B was more effective.

Discussion

Since there are several types of rehabilitation and the physician may need to direct the patient to the most suitable rehabilitation program(s), rehabilitation for LBP is in and of itself a difficult topic. The TBC paradigm classifies rehabilitation into three basic categories: symptomatic, motor control, and functional. For new or recurring bouts of LBP with prominent symptomatic characteristics, symptomatic treatment is used. Patients with mild disabilities and discomfort should use movement control. The functional approach, which tries to address functional impairment, is helpful for people with mild LBP and disability [8].

There were two groups of 50 individuals each in the current study's total participation of 100 subjects. While the control group (Group B) received standard saline water based sprays + traditional physiotherapy care, the experimental group (Group A) received transdermal application of Mg oils + traditional physiotherapy management. In the current study, which was divided into age groups 31, 31-40, and 41-50 and comprised 24, 24, and 31 patients correspondingly, there were a total of 43 men and 57 females.

The amount of magnesium in a person's body is also influenced by their gender since both soft and hard tissues may more easily absorb magnesium thanks to oestrogen. Because young women retain magnesium better than young males, their circulation magnesium levels are lower, especially during ovulation or while using an oral contraceptive, when oestrogen levels are at their peak. As a result, samples collected from populations with a mix of sexes or at intervals that don't take this into account may further skew research on human magnesium [9].

In Group A, the participants were divided into three age groups (31, 31-40, and 41-50), totaling 15, 17, and 18 patients, respectively, of which 22 were men and 28 were women. While in Group B, patients were included according to age (31, 31-40, and 41-50), with 9, 28, and 13 patients, respectively, of which 21 were men and 29 were women.

The success of the therapy Pain using the back disability using QUEBAC and flexibility using the sit-and-reach test were all assessed according to the protocol at baseline (0th day), Post-intervention -1 (10th day), and Post-intervention-2 (20th day) in both groups.

The Hamstring flexibility was assessed on sit & reach test at baseline (0^{th} day), Post-intervention -1 (10^{th} day) & Post-intervention-2 (20^{th} day) and the Mean and Standard Deviation (SD) values at different intervals of Group A were 11.63±3.31, 10.38±2.63 & 9.84±2.47 respectively while in Group B were 13.27±3.23, 11.82±3.06 & 11.19±3.26 respectively. The MD values at (0 -10^{th}) days, (0 -20^{th}) days & (10 -20^{th}) days Group A were 1.25±1.29, 1.79±1.68 & 0.54±0.86 respectively, While Group B MD values at (0-10^{th}) days, (0-20^{th}) days & (10-20^{th}) days were 1.45±1.28, 2.08±1.46 & 0.64±0.87 respectively.

The statistically significant improvement in flexibility on sit & reach test was seen in both the groups when compared at three intervals- 0 vs 10^{th} day, 0 vs 20^{th} day & 10^{th}vs 20^{th} day. The t-value at p<0.001 in Group A at 0 vs 10^{th} day, 0 vs 20^{th} day & 10^{th}vs 20^{th} day was 6.87, 7.53&4.56 respectively while in Group B was 7.97, 10.07 & 5.15 respectively. The flexibility was significant improved in Group A as comparatively to Group B when we compared the mean value and mean difference of Group A VS Group B. The t-value at 0^{th} day on 10^{th} day & 20^{th} day (<0.001) were 2.51, 2.52 & 2.33 respectively when compared Group A vs Group B which signifies statistically significant improvement in the flexibility.

ISSN:0975 -3583,0976-2833 VOL14, ISSUE 04, 2023

We concluded from the present study that the significant changes were seen in pain, back disability, serum mg levels and flexibility when assessed on different variables in patients who undergone the transdermal application of Mg oil than patients who received normal saline application spray.

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