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Efficacy of High Dilution Medicines in combination with physiotherapy in trauma induced low back pain- A Randomized Control Clinical Trial

Research Article

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Abstract

Background: Lower back pain can refer to a wide range of back injuries or conditions and is one of the most common musculoskeletal disorders which necessitating health care and one of the reason for which many seek a family physician which is cause for limited range of motion. Homoeopathic medicines can offer long term relief from the backache. Methods: This is a three arm randomized controlled trial. Total 30 patients with trauma-induced low backache were chosen at random and divided equally into three study groups. Group A (n=10) was given Arnica 200 twice a day for the first 15 days, after 15 days, another evaluation was performed, and the dose was repeated as needed. Group B (n=10) received constitutional medicine. The dose of constitutional medicine was repeated as needed. After careful case taking, case working, and repertorisation, *Bryonia Alba Linn., Rhus Toxicodendron Linn., Nux Vomica Linn*. were administered on a constitutional basis. Group C (n=10) received a placebo. All the three groups received physiotherapy to strengthen back muscles in order to reduce the likelihood of recurrenceData was anlaysed using STATA software using Chi square test, ANOVA and post-hoc Bonferroni Multiple comparison test. Results- Significant improvement in pain scores (VAS) was observed in both between the group and within the group comparisons and the effect was more pronounced in Group B. Conclusion: Hence we conclude that an individualized approach is more effective in the management of patients with trauma-induced low back pain.

Key Words: Trauma induced low backache, Arnica Montana, Constitutional prescription, Physiotherapy, Isometric exercises, Individualized approach.

Introduction

Low back pain is one of the highest prevalence problems of public health. It affects up to 85% people worldwide.(1) Low back pain can be the result of many different things. Pain can be triggered by some combination of overuse, muscle strain, trauma and/or injuries to the muscles, ligaments, and discs that support the spine. Over time, a muscle injury that has not been managed correctly may lead to an overall imbalance in the spine. This can lead to constant tension on the muscles, ligaments, bones, making the back more prone to injury or re-injury.(2) The 80% of the population suffer range of motion low back pain at least once or twice in a life time. Low Back Pain is known to be induced by tissue damage, muscle weakness, and psychological factor, etc. Most of patients with LBP show weakened muscle strength in lumbar spine area. Increasing strength of lumbar muscle is the most important therapeutic modality for the patient with Low Back Pain. (3) Isotonic, isokinetic, and isometric exercise has been used to improve muscle strength and endurance of muscles in lumbosacral area. Isometric exercise is safe and has potent efficacy for increasing muscle strength, and it can apply to the patients with motion limitation. Mat exercise is the most used type of isometric exercise and proved to be effective in improving lower back muscle strength.(4,5)

Following the exclusion of diseases and emergencies, homoeopathy can be used in conjunction with physiotherapy to treat traumatic low backache. Depending on the circumstances, homoeopathy might be provided as an acute totality or as an individualized prescription. In the treatment of musculoskeletal diseases, homoeopathic remedies such as Arnica Montana, Bryonia Alba, and Rhus Toxicodendron are quite beneficial.

Individualized homeopathy "is one of several types of homeopathy," which aims to "capture a person's individuality," and then a homeopathic remedy

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is chosen based on symptoms, especially those with "unusual or unique patterns."

Pathophysiology

Individualization necessitates a comprehensive grasp of a live organism's whole response to a hostile environment. The signs and symptoms of this whole response include emotional, intellectual (spiritual), and physical realms where the vital force reveals itself.

A homoeopath does not specialize in treating arthritis, bronchitis, or cancer, for example. To put it another way, he doesn't just treat sore joints, inflamed bronchi, or cancerous growths. Rather, he addresses the mental, emotional, and physical components of a person suffering range of motion arthritis, bronchitis, cancer, and other ailments. Each patient is treated as a unique individual in homoeopathy; for example, a person with hepatitis can receive several homoeopathic remedies, each aimed at the individual's totality of symptoms rather just his liver. (6)

Homoeopathic medicines are prescribed on the basis of Individualization, which is tailoring the remedy according to the individual's needs. It means every individual is different range of motion others in some way; be it his stature, talking, choices, behavior, or his susceptibility to diseases.(7)

It is a well known fact that Arnica Montana is a well-known trauma and pain treatment used in traditional medicine, and homoeopathy. According to the anthroposophical medical philosophy, it is used to treat inflammation by increasing body temperature and modulating the neurosensory system. Treatment with anthroposophical injectable low-potency *Arnica Montana* showed to be safe, effective and cost-effective in acute and consolidation treatment of low back pain.(8,9)

Methods

In this study subjects were recruited after Ethical Clearance from the Institutional Ethics Committee. This is a three arm randomized controlled trial. Total 30 patients with trauma-induced low backache were chosen at random and divided equally into three study**.** Group A received daily dose of Arnica 200 twice in a day for first 15 days and physiotherapy for strengthening of back muscles to lessen the chances of recurrence. After 15 days further assessment was done and repetition of dose was done as per requirement Group B received constitutional medicine and physiotherapy for strengthening of back muscles to lessen the chances of recurrence repetition of dose of constitutional medicine was done as per requirement. Group C received placebo and physiotherapy for strengthening of back muscles to lessen the chances of recurrence. Goniometer for range of motion and Visual analogue scale for pain assessment were used for assessment. The outcome measures were assessed pre treatment on Day 1 and immediately after the treatment.

Inclusion criteria

- The volunteers were between 20 to 40 years of age and of both sexes, so that bodily degeneration that comes with age will not be a serious factor.
- The volunteer were intelligent enough to properly appreciate and record the symptoms as deviations during case taking and follow ups.
- Cases of backache due to trauma were included in the trial; all other causes of backache were excluded.
- Relevant investigations were done to rule out any other cause of backache.

Exclusion criteria

- Pregnant and lactating mothers or women under any treatment using
- People who are have undergone any surgery on spine were excluded, congenital anomalies of spine
- HIV positive, bleeding disorders were excluded
- HbsAg positive were omitted.

Procedure

The patients were divided in 03 groups. Group A, Group B and Group C had 10 patients each. Patients were randomly allotted in the group. At the beginning of the study case history of the patients was taken and relevant investigations were done to rule out other causes of backache. All patients received daily session of physiotherapy of 20 minutes along with Homoeopathic consultation. Group A received daily dose of Arnica 200 twice in a day for first 15 days and physiotherapy for strengthening of back muscles to lessen the chances of recurrence. After 15 days further assessment was done. Repetition of dose was decided accordingly. Group B received constitutional medicine and physiotherapy for strengthening of back muscles to lessen the chances of recurrence. Repetition of dose in follow up were as per susceptibility and sensitivity of the patient Group C received placebo and physiotherapy for strengthening of back muscles to lessen the chances of recurrence. Written well informed consent was taken from each volunteer before starting the research project. The time period of the study was 6 months to 1 year. 40 no globules were used for medication and were dispensed in plastic bottles. Instructions about dosage and storage of medicines were given to all the patients.

Procedure for performing isometric exercises

Patients were instructed to lie on their backs on a mat, knees up with feet flat on mat and was told to pull the abdominal muscles in and push their low back to the mat. Repeat 20 times. This static back exercises was done on every session.

Data Analysis

Data was coded and analysed in STATA (version 10.1,2011)software by StataCorp, Texas,USA. Skewness and Kurtosis test for normality was performed where only post test (Day 15) values were found skewed, however pre-post differences validated normality assumptions. Hence parametric tests like One way ANOVA (F-test), post hoc Bonferroni multiple comparion test, paired t test were used for comparison of means. Pearson's Chi-Square (non-parametric) test was used to compare qualitative variables like gender. Significance level was set at alpha=0.05.

Observations and Results

Table 1: Comparison of demographic variables in study groups

Variables	Summary				
	Group (n)	Mean	SD	Test statistics	P value
Age (years)	A (n=10)	34.40	9.902	F = 0.16	0.85 Not significant
	B (n=10)	32.30	5.143		
	C (n=10)	33.40	8.822		
Gender	Category	Male - No. (%)	Female - No. (%)	Test statistics	P value
	A (n=10)	5 (50.00)	5 (50.00)	χ^2 =1.09	0.58 Not significant
	B (n=10)	3 (30.00)	7 (70.00)		
	C (n=10)	5 (50.00)	5 (50.00)		

Table 2: Comparison of pre- and post-test range of motion flexion (degrees) in the three study groups

Groups	n	Pre (Day 1)	Post (Day 15)	Difference (Day 15 - Day1)	P Value**
		Mean± SD	Mean± SD	Mean± SD	Within-the-group comparison
Group A	**10**	44.4± 12,9	58.9 ± 1.2	14.5± 12.1	0.043, Significant
Group B	**10**	41.9± 7.9	57.5± 2.9	15.6± 7.2	0.001, Significant
Group C	**10**	44.4± 10.4	56.1± 1.4	12.1± 10.0	0.004, Significant
P Value* Between-the-group comparison		0.832 Not significant	0.038 Not significant	0.727 Not significant	
*ANOVA, ** Paired t-test					

Table 3: Comparison of range of motion extension (degrees) between pre- and post-test in three study groups

Groups	n	Pre (Day 1)	Post (Day 15)	Difference (Day 15 - Day1)	P Value**
		Mean± SD	Mean± SD	Mean± SD	Within-the-group comparison
Group A	**10**	17.7± 5.9	24.4 ± 1.1	6.7± 5.2	0.003, Significant
Group B	**10**	21.7± 4.2	24.3± 1.1	2.6± 4.4	0.095, Not Significant
Group C	**10**	18.7± 5.1	23.6± 1.7	4.9± 5.1	0.014, Significant
P Value* Between-the-group comparison		0.211 Not significant	0.349 Not significant	0.192 Not significant	
*ANOVA			** Paired t-test		

Table 4: Comparison of VAS scores between pre- and post-test in three study groups

Groups	n	Pre (Day 1)	Post (Day 15)	Difference (Day 15 - Day1)	P Value**
		Mean± SD	Mean± SD	Mean± SD	Within-the-group comparison
Group A	**10**	7.2± 1.3	2.3 ± 0.9	4.9± 1.4	0.001, Significant
Group B	**10**	7.6± 1.0	1.9± 0.8	5.7± 1.3	0.001, Significant
Group C	**10**	7.1± 0.7	3.7± 0.8	3.4± 0.7	0.001, Significant
P Value* Between-the-group comparison		0.528 Not significant	0.001 Significant	0.004 Significant	
*ANOVA			** Paired t-test		

Table 5: Pair-wise comparisons of mean changes (from Day1 to Day 15) in flexion (degrees), extension (degrees) and VAS scores

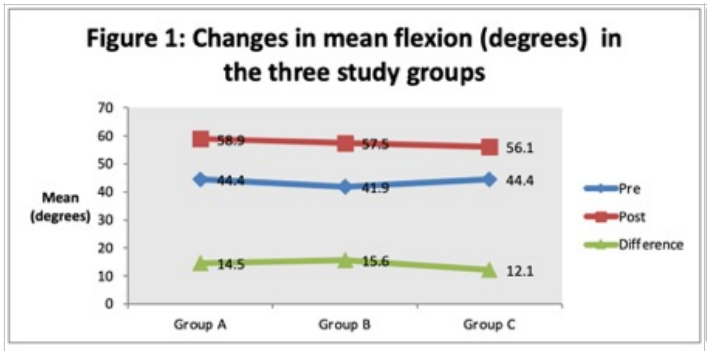
Pair-wise comparison groups	No. of pairs	ROM Flexion	ROM Extension	VAS
		Mean change ± SEM	Mean change ± SEM	Mean change ± SEM
Group Avs B	**10**	1.1± 4.4 95% CI (-8.2 - 10.4)	-4.1 ± 2.2 95% CI (-8.6 - 0.4)	-0.8± 0.6 95% CI (-2.1 - 0.5)
Group Bvs C	**10**	-3.5± 3.9 95% CI (-11.7 – 4.7)	2.3± 2.1 95% CI (-6.8 - 2.2)	2.3± 0.5* 95% CI (1.3 - 3.3)
Group A vsC	**10**	1.1± 4.4 95% CI (-12.8 - 8.0)	-1.8± 2.3 95% CI (-6.6 - 3.0)	1.5± 0.5* 95% CI (0.5 - 2.5)

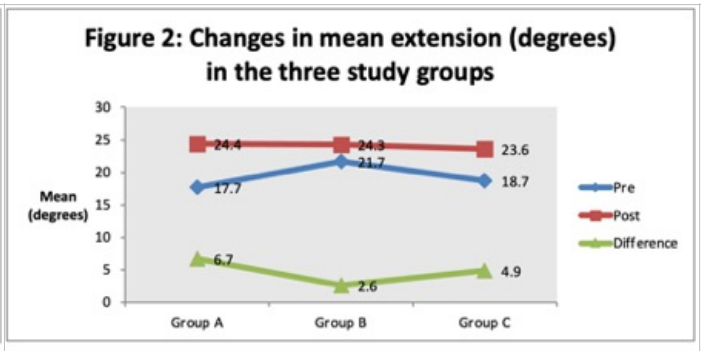
* Signifcant on Post hoc Bonferroni Multiple Comparison test, P <0.05

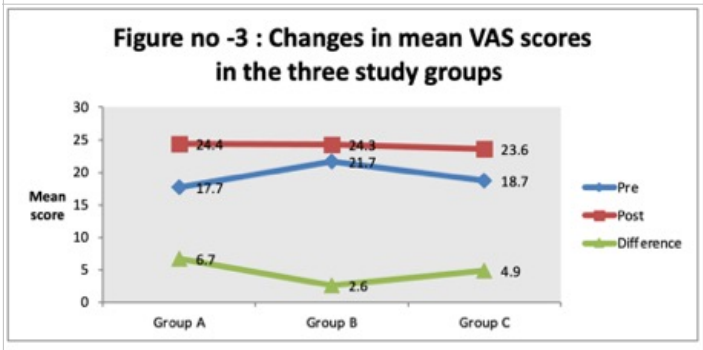
SEM = Standard Error of Mean, CI =Confidence Interval

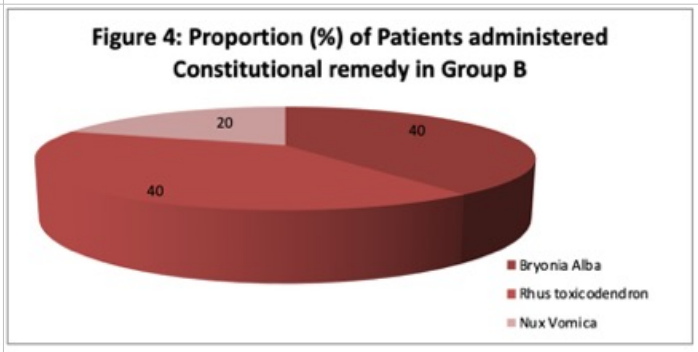
Table 6: Constitutional remedies used by Group B

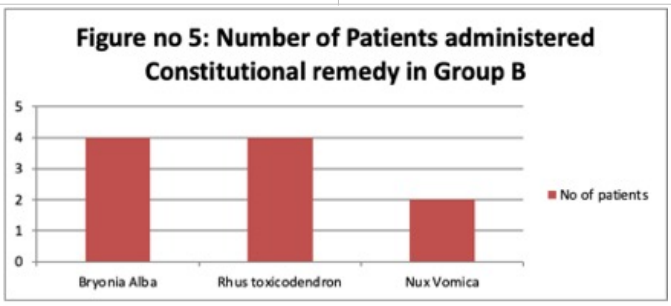
Name of Constitutional remedy used in Group B	Number of patients
Bryonia Alba	4
Rhus Toxicodendron	4
Nux Vomica	2











Results

Demographic characteristics of study subjects like age, gender were found comparable across all the three treatment groups.

Pre –post changes in mean flexion in study subjects within each group were found statistically significant, and Group B showed highest changes. However these changes were found comparable across all the three treatment groups.

Pre-post changes in mean extension in study subjects within each group were found statistically significant, and group A showed highest changes. However these changes were found comparable across all the three treatment groups.

Pre post changes in mean VAS scores in study subjects within each group were found statistically significant and Group B showed highest changes. Moreover these changes were found comparable across all the three treatment groups on baseline i.e. Day 1 but significantly reduced on Day 15 in all three groups.

There is no difference in improvements in two range of motions parameters i.e flexion and extension across three treatment groups; though within the group significant differences were observed for these parameters in each group. But significant improvement in pain scores(VAS)was observed in both between the group and within the group comparisons, and the effect was more pronounced in Group B.

Discussion

As per our review of literature there is no such study done previously .Patients were assessed pre treatment and post treatment with help of Goniometer for range of motion and Visual analogue scale for pain assessment .All groups show significant relief in pain. But the group which received constitutional medicine along with help of physiotherapy showed significant relief as compared to other groups. In Group B constitutional remedies like Bryonia AlbaLinn, *Rhus toxicodendron* Linn. and *Nux Vomica* Linn. were administered. Hahnemannian guidelines were followed during potency selection and administration. Individualised homeopathic treatment represents an effective treatment for low back pain and other

diagnoses. It improves health-related quality of life and reduces the use of other healthcare services.[10]The same study needs to be replicated on larger sample size, for better understanding of the efficacy between the groups.

Conclusion

The constitutional medicine group (group B) was found to be effective in pain management. In all groups, the pain score significantly reduced .clinically, patients in all groups improved, but those in Group B, when constitutional medicine was administered, improved far more than those in the other groups. As a result of this study, we may infer that an individualized strategy aids in the therapy of traumatic low backache. Hence we conclude from this study that individualized approach is more useful in management of patients with trauma induced low back pain.

Conflicting Interest (If present, give more details):

The authors declare no conflict of interest.

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Ethical Statement

Written informed consent was taken from every patient at the commencement of study.

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