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Conservative Treatment of Low back Pain in Lumbar Disc Herniation: Comparison of Three Therapeutic Regimens

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ABSTRACT

Purpose: This study aimed to compare three conservative therapeutic regimens among cases with acute lumbar disc herniation (LDH).

Methods: This is a cross-sectional study which was done among patients with previous definitive diagnosis of LDH who received at least one-year conservative treatment and aged 20-75 years. Based on the type of medication consumption which documented in medical records, the participants were divided into three groups including GA, GN and GNP. The GA group was subjected to physical therapy (ten sessions per month), as well as gabapentin (100 mg/daily); the GN group had received naproxen (500 mg, twice daily), along with gabapentin and physical therapy; and the GNP group received prednisolone (5 mg, twice daily) and naproxen, alongside gabapentin and physical therapy. The Oswestry Disability Index (ODI) was applied for evaluating functional improvement of participants, before and after treatments.

Results: among 547 participants, 202 (36.9%), 171 (31.2%) and 174 (31.9%) belonged to GA, GN and GNP groups, respectively. Overall, 374 (68.4%) participants were female. The average age of the study groups was 57.8 (10.5), 55.7 (11.8), and 57.3 (11.2) years in the GA, GN, and GNP groups, respectively. The between-group analysis showed a significant decrease in the ODI score in the GNP group, compared to GA (P<0.001) and GN (P=0.04) groups. No significant difference was observed in the overall ODI score between the GA and GN groups. Nevertheless, comparison of these two groups showed significant differences in two sections of ODI, that is, pain intensity (P<0.001) and social life (P=0.005).

Conclusion: Long-term use of low-dose oral corticosteroids alongside other medications, could produce satisfactory clinical outcomes in the conservative management of acute low back pain.

Keywords: Disc herniation; Acute low back pain; NSAIDs; Gabapentin; Oral corticosteroids

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BACKGROUND

Lumbar disc herniation (LDH) is as the commonest causes of acute and chronic low back pain (LBP), with a lifetime incidence of 30% [1]. According to the literatures, LDH is one of the leading causes of disability around the world in the past two decades [2-4]. The high direct and indirect medical costs, due to LDH in healthcare systems, are among burdens imposed by the disease on patients [5, 6]. Therefore, proper management should be considered to reduce the health and economic burdens of LDH.

Generally, non-surgical management is considered as the first-line treatment for acute LBP. Although various therapeutic agents have been identified and prescribed for the treatment of acute LBP, unsatisfactory clinical outcomes may be achieved. In non-surgical management of LDH, various medicines, such as non-steroidal anti-inflammatory drugs (NSAIDs), systemic steroids, opioids, anticonvulsants, and antidepressants, are currently used to relieve the pain. However, differences in the clinical efficacy, advantages, and side effects of the mentioned agents have caused some challenges in the process of physicians' decision-making, and there is no standard therapeutic regimen [7]. Also, there is a paucity of well-designed studies to evaluate the optimal conservative management of LBP [8]. Therefore, this study aimed to compare three conservative therapeutic regimens, which are widely prescribed for patients with acute LDH.

MATERIALS AND METHODS

In the present study, all of the patients' data, including their identity and personal information, were kept confidential. Moreover, before study, informed constant forms were obtained from the volunteers, and they were allowed to leave the research whenever they want.

Study sample

The current retrospective cross-sectional study was performed between September 2018 and October 2019 in Poursina Hospital in Rasht, Iran. This is both a teaching and referral center for orthopedic procedures which affiliated to GUMS.

Patients and Methods

The present research was done on cases who previously were visited at outpatient orthopedic clinic of Poursina hospital and had definitive diagnosis of LDH. The diagnosis of LDH was made by expert orthopedic surgeons using evidences of LDH and spinal cord compression in magnetic resonance imaging (MRI). All of the patients aged 20-75 years with diagnosis of LDH who received conservative treatment for at least one year were eligible to participate in the study. The patients with evidence of cauda equina syndrome, focal neurologic deficit, history of trauma, spinal surgery, rheumatoid arthritis (RA); ankylosing spondylitis and osteoporosis were excluded from the study. Moreover, the clients who

did not take the prescribed medications regularly for at least one year due to side effects or failure to adherence, did not allowed to participate in the study.

Based on patients' treatment regimen in documented medical records, the clients were assigned into three groups including GA, GN and GNP. The patients in GA group had received 100 mg of gabapentin per day for at least one year. Moreover, the patients in GN and GNP groups had received naproxen (500 mg/two times a day) along with gabapentin and prednisolone (5 mg/twice daily) along with naproxen and gabapentin, respectively. Moreover, routinely, all of the patients with LBP had been prescribed physical therapy with same modality for ten sessions per month. Finally, the data were collected through face-to-face interview sessions or telephone contacts by trained general practitioners.

First, the socio-demographic characteristics of the participants, including gender, age, and occupation during last year, were determined. Next, the participants were asked about their functional disability, before and after treatments. In order to assess the functional disability and possible improvement of participants, Oswestry Disability Index (ODI), which is regarded as the gold standard tool for evaluating low back functional outcomes [9], was used. Generally, ODI evaluates ten domains of daily life, which can be affected by low back pain, as shown in detail in Table 2. This index divides the participants into five groups in terms of disability, that is, minimal, moderate, severe, crippled, and bedridden.

2.3. Data analysis

Data were analyzed by SPSS 26 using Chi-square test for evaluating qualitative variables at $P<0.05$. Also, differences in the mean scores between two groups and three groups were analyzed, by independent sample t-test and one-way analysis of variance (ANOVA), respectively.

RESULTS

Among 647 cases who met the inclusion criteria, 615 volunteers (95.0% response rate) agreed to take part in the research. However, 57 patients were excluded from the study due to irregular use of medications. Moreover, 11 patients left the study due to personal reasons. Figure 1 shows the research flowchart. Finally, of 547 (88.9%) participants who completed the study, 202 (36.9%), 171 (31.2%) and 174 (31.9%) patients belonged to the GA, GN and GNP groups, respectively. Among all participants, 374 (68.4%) were female, and 173 (31.6%) were male. The average age of the subjects was 57.8 (10.5), 55.7 (11.8), and 57.3 (11.2) years in the GA, GN, and GNP groups, respectively. No significant difference was observed in the average age between the three groups. The socio-demographic characteristics of the participants are presented in detail in Table 1.

Before use of medications, of all participants, 450 (82.3%) were severely disabled, 69 (12.6%) were moderately disabled, and 28 (5.1%) were minimally disabled. No significant difference was detected regarding disability in participants before use od medications. The mean (SD) total ODI score was 44.6 (8.6), 45.2 (16.9), and 49.2 (17.1) in the GA, GN, and GNP groups, respectively. No significant difference was detected in the average total ODI score and its sections among groups at baseline. The total ODI scores and the score of each domain are presented in detail in Table 2.

Figure 1. The research flowchart

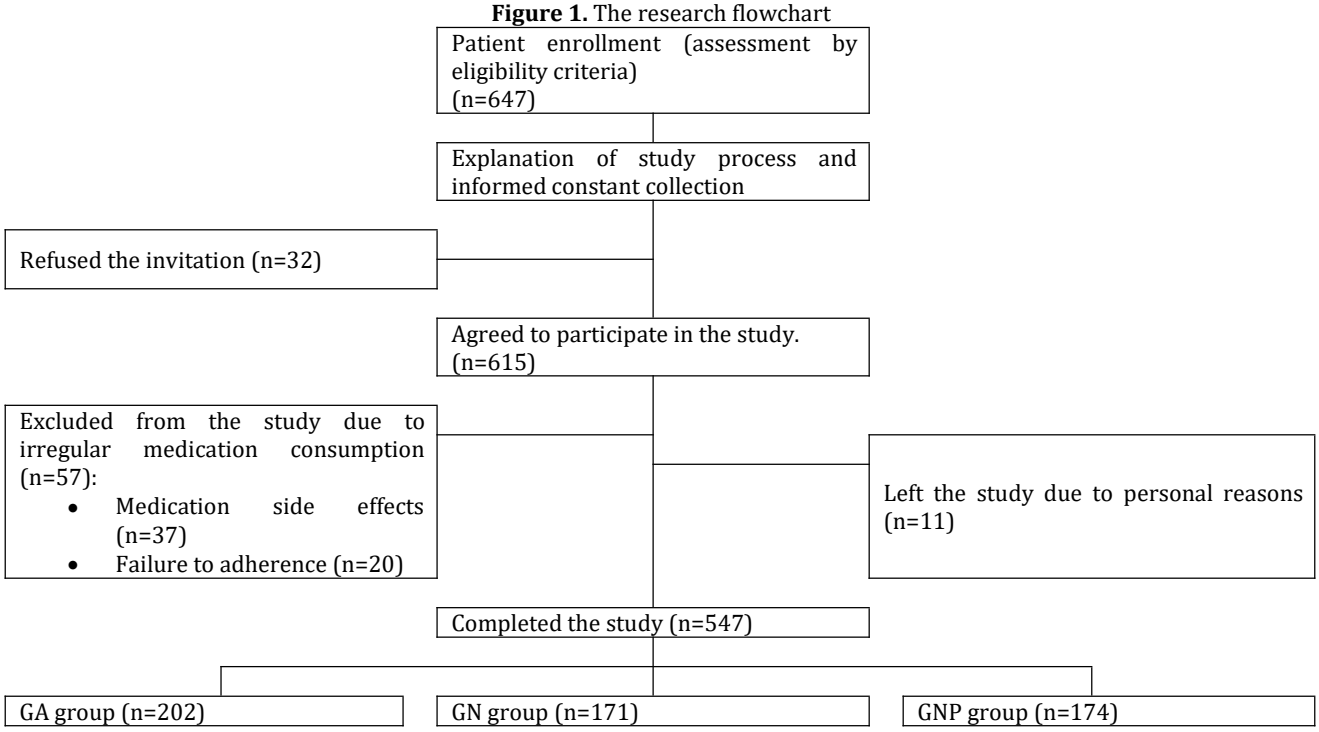

Table 1. The results of descriptive analysis of sociodemographic variables amng study groups

Variables		Study groups			P-value
		GA group (n=202)	GN group	GNP group	

			(n=171)	(n=174)	
Age (SD)		57.8 (10.5)	55.7 (11.8)	57.3 (11.3)	0.16
Sex	Male (%)	85 (49.2)	44 (25.4)	44 (25.4)	0.24
	Female (%)	117 (31.3)	127 (33.9)	130 (34.8)	
Work	Heavy (%)	61 (49.1)	35 (28.3)	28 (22.6)	0.02*
	Easy (%)	143 (34.3)	140 (33.4)	135 (32.3)	
	Workless (%)	3 (60.0)	1 (20.0)	1 (20.0)	

*P<0.05

Table 2. The descriptive analysis of ODI scores in the study groups before use of medications

Mean (SD) ODI score	Study groups			P-value
	GA group (n=202)	GN group (n=171)	GNP group (n=174)	
Pain intensity	7.4 (1.5)	7.3 (1.6)	7.4 (1.3)	0.66
Personal care	7.4 (1.4)	7.4 (1.2)	7.3 (1.4)	0.85
Lifting	6.5 (1.8)	6.4 (2.2)	5.7 (1.9)	0.45
Walking	3.3 (1.6)	2.7 (1.5)	4.2 (1.4)	0.68
Sitting	3.8 (0.9)	3.0 (1.5)	2.6 (2.8)	0.07
Standing	7.4 (1.4)	7.4 (1.2)	7.4 (1.5)	0.37
Sleeping	2.1 (1.3)	2.2 (1.0)	2.4 (4.4)	0.08
Sex life	4.1 (2.2)	4.1 (2.1)	4.3 (3.5)	0.12
Social life	5.6 (2.9)	5.7 (4.1)	5.9 (3.8)	0.73
Travelling	2.7 (1.6)	2.8 (1.4)	3.0 (1.4)	0.18
Total	44.6 (8.6)	45.2 (16.9)	49.2 (17.1)	0.50

*P<0.05

After consumption of medications, the mean (SD) total ODI scores were 28.4 (8.8), 17.1 (15.8), and 15.7 (18.2) in the GA, GN, and GNP groups, respectively. The within-group analysis showed a significant reduction in the total ODI score among the study groups (P<0.001). Moreover, the between-group analysis revealed that the total ODI score of the GNP group significantly decreased, compared to the GA and GN groups (P<0.001 and P=0.04, respectively). Nevertheless, the between-group analysis demonstrated no significant reduction in the total ODI score between the GA and GN groups (P=0.66). The patients in the GN group obtained significantly lower ODI scores in only two sections of ODI, including pain intensity (P<0.001) and social life (P=0.005), than the GA group. The mean scores of all ODI sections in the GNP group were significantly lower compared with the GA group. Except for lifting and sitting, the mean scores of all ODI sections in the GNP group were significantly lower compared with the GN group. The ODI scores of the study groups after 12 months of intervention are presented in detail in Table 3.

According to ODI, the disability status of the participants changed significantly. The number of severely disabled patients decreased from 450 (82.2%) to 4 (0.7%) after treatment. Also, the number of moderately disabled and minimally disabled patients was 262 (47.9%) and 281 (51.4%), respectively. The disability status of the patients in the three groups was significantly different after the research (P<0.001). Among minimally disabled patients, 170 (60.5%) belonged to the GNP group, whereas 23 (8.2%) and 88 (31.3) belonged to the GA and GN groups, respectively. No severely disabled patient was found in the GNP group after 12 months of treatment with medications. Table 4 shows the disability status of the participants after treatment.

Table 3. The results of descriptive analysis of ODI scores in the research groups after treatment

ODI score mean (SD)	Study groups			P-value		
	GA group (n=202)	GN group (n=171)	GNP group (n=174)	GA vs GN	GA vs GNP	GN vs GNP
Pain intensity	5.4 (2.2)	3.2 (3.3)	0.2 (0.1)	<0.001*	<0.001*	<0.001*
Personal care	5.1 (2.2)	3.2 (3.1)	0.3 (0.2)	0.07	<0.001*	<0.001*
Lifting	5.3 (1.9)	3.3 (2.9)	0.3 (0.1)	0.06	<0.001*	0.06
Walking	1.8 (0.85)	1.1 (1.2)	0.1 (0.1)	0.08	<0.001*	<0.001*
Sitting	1.8 (0.8)	1.0 (1.2)	0.08(0.01)	0.30	<0.001*	0.07
Standing	5.1 (2.2)	3.2 (3.1)	0.3(0.1)	0.09	<0.001*	<0.001*
Sleeping	0.2 (0.7)	0.2 (0.7)	0.01 (0.01)	0.99	0.001*	0.002*
Sex life	3.5 (1.3)	2.1 (2.2)	0.1 (0.5)	0.06	<0.001*	<0.001*
Social life	2.4 (1.7)	2.1 (1.8)	0.1 (0.01)	0.005*	<0.001*	<0.001*
Travelling	2.0 (1.1)	1.2 (1.3)	0.1 (0.5)	0.09	<0.001*	<0.001*
Overall	28.4 (8.8)	17.1 (15.8)	15.7 (12.2)	0.66	<0.001*	0.04*

*P<0.05

Table 4. The results of descriptive analysis of the patients' disability status after treatment

Disability status	Study groups	P-value

(%)	GA group (n=202)		GN group (n=171)		GNP group (n=174)		
	0	12th	0	12th	0	12th	
Minimal	8 (28.5)	23 (8.2)	14 (50.0)	88 (31.3)	6 (21.5)	170 (60.5)	
Moderate	26 (37.6)	178 (67.9)	19 (27.6)	80 (30.5)	24 (34.8)	4 (1.5)	<0.001*
Severe	168 (37.3)	1 (25.0)	138 (30.7)	3 (75.0)	144 (32.0)	0 (0.0)	

*P<0.05

DISCUSSION

Our findings indicated that all our three therapeutic regimens, which were used to treat patients with LBP, had significant effects by the end of the study. Moreover, the effect of prednisolone administration, alongside gabapentin and naproxen, on LBP was dramatically higher than the other two therapeutic regimens without prednisolone. The patients in the GNP group obtained lower scores in all sections of ODI, compared to the other groups. These findings showed that long-term use of low-dose prednisolone in combination with other regimens not only reduced the pain intensity, but also improved the general functionality of patients; the disability status of patients in the GNP group relative to the other groups emphasizes this finding.

Nevertheless, we could not find any study evaluating the effect of long-term low-dose oral corticosteroids on the treatment of LBP caused by LDH. Some attempts have been made to assess the short-term application of oral corticosteroids. In this regard, Goldberg et al. [10] evaluated the effect of a tapered high dose of prednisone in a 15-day intervention among patients with acute sciatica. The patients were prescribed cumulative doses of prednisone (600 mg) for 15 days (60 mg, 40 mg, and 20 mg, each for five days). These findings showed that short-term use of prednisone could modestly improve the function of patients and had no effects on pain.

In another study, Ko et al. [11] showed that short-term application of triamcinolone (4 mg twice daily for two weeks) was significantly more beneficial in pain relief, compared to pregabalin or gabapentin among patients with radiating lumbar pain. These evaluations showed that application of high-dose oral corticosteroids could be beneficial to manage cases with acute sciatica. However, short-term administration of high-dose corticosteroids, due to its adverse effects, has limited the physicians in prescribing systemic corticosteroids broadly. Previously, it was found that long-term use of low-dose oral corticosteroids (≤5 mg/day) could significantly decrease their side effects [12]. Nevertheless, some evidence suggests that certain adverse effects persist, even with dose reduction [13, 14]. Therefore, dramatic response of patients to oral corticosteroids in our study showed that these agents could be regarded as an alternative therapy for cases with LBP, considering the risk-benefit ratio.

Moreover, our research revealed no significant difference in the application of gabapentin alone or in combination with naproxen. Use of naproxen could only reduce the pain intensity and had no significant impacts on the general functionality of cases. Also, PD Roelofs et al. [15], in their review of 65 trials, revealed that NSAIDs could be beneficial in short-term symptomatic relief of cases with acute and chronic LBP. They demonstrated no significant difference between specific types of NSAIDs. However, it seems that cyclooxygenase 2, as a selective NSAID, had fewer adverse effects than non-selective NSAIDs [16]. This finding, which is in line with our study, revealed that NSAIDs can be only effective in reducing the pain intensity of patients with LBP. Nonetheless, there are still some controversies about the application of NSAIDs in LBP.

Additionally, Majchrzycki et al. [17] showed that concurrent consumption of NSAIDs and deep tissue massage associated with LBP reduction to the same degree that deep tissue massage alone did. Also, in another review, no significant difference was reported between NSAIDs and placebo in reducing the pain of patients with LDH [18]. However, these studies considered pain alleviation in a short-term follow-up, whereas our results showed a significant decrease in pain during at least one-year treatment. Overall, as NSAIDs are frequently prescribed by physicians, the observed controversies and side effects should be considered in the management of patients with LBP.

This study had two limitations. First, the physicians were not blind to the severity of LBP of patients for medication prescription. Hence, the medications were prescribed according to severity of their pain. Second, the excluded participants who use the medications irregularly due to side effects were not evaluated in terms of the kind of medication. Since there is still contradictory findings regarding side effects of long-term and low-dose oral corticosteroids, it is recommended that future studies try to demonstrate its exact side effects.

CONCLUSION

The present study revealed that long-term integration of low-dose oral corticosteroids to the treatment regimen of patients with LBP could not only reduce the pain intensity of patients, but also improve the total functionality of patients in life. Moreover, the results showed that addition of naproxen to the therapeutic regimen of patients with LDH could only improve their pain intensity and had no positive effects on their functionality status.

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