Evaluation of Perifacet Injections and Paraspinal Muscle Rehabilitation in Treatment of Low Back Pain. A Randomised Controlled Trial

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SUMMARY

Background. Lumbar paraspinal muscle dysfunction and Low Back Pain are strongly correlated. The best treatment for non-specific Low Back Pain is still controversial. To evaluate the efficacy of lumbar multifidus muscle retraining exercises and perifacet multifidus injections in the treatment of Low Back Pain.

Material and methods. 63 patients with non-specific LBP, with or without leg pain, and magnetic resonance images of paraspinal muscle degeneration only, were randomised to one of three treatment groups: A - Back education and standard physiotherapy for 10 weeks, B - Back education and gym ball exercise for 10 weeks or C - Perifacet injection into the lumbar multifidus muscle with methylprednisolone. The Oswestry Disability Index was used as the primary outcome measure and the SF-36, modified Zung depression index, modified somatic perception and McGill pain questionnaires were used as secondary outcome measures.

Results. 56 patients completed the trial. The Oswestry Disability Index improved in general from a mean of 29.9 to 25.9, but there were no statistically significant differences between the groups. Low back pain improved most in group C (P<0.02), while physical activities and social functioning were improved the most in group B (P<0.03).

Conclusion. Perifacet injection and back education including a gym ball exercise program may be more effective than back education alone in relieving pain and improving physical capacity respectively. Back education including gym ball exercise could be used for non-specific Low Back Pain, as the ultimate goal should be to restore function.

Key words: multifidus, rehabilitation, perifacet injection, low back pain

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BACKGROUND

Low back pain (LBP) is a major health problem. The role of paraspinal muscle dysfunction in LBP has been extensively studied [1-4]. It is believed that the paraspinal muscles, especially the multifidus, play a key role in stabilisation of the spine [5] and it has been shown that multifidus muscle degeneration is common in chronic LBP [6].

Physiotherapists apply different methods and techniques in treating patients with LBP. The effectiveness of most of these treatment modalities has not yet been established in a randomised controlled study [7,8]. In recent years, major developments in research and a better understanding of the role of paraspinal muscles in LBP patients have led to a more specific exercise strategy. It is thought that this approach is more effective in influencing the recovery of paraspinal muscles and LBP. Various programs have been proposed to promote lumbar stabilisation [9-12]. However, the value of these exercises in recruiting the key stabilising muscles in the lumbar spine, like the multifidus, has been difficult to establish. The best exercise regime is not yet known.

There has been a considerable increase in the use of the gym ball or Swiss ball as an exercise tool in the last several years [11,13]. Gym ball exercise has been found to recruit and increase the water content of paralumbar spinal muscles [14]. This has led to successful activation of deep lumbar muscles in healthy volunteers following 10 minutes flexion and extension exercise using gym ball. Learning to perform the exercise on the gym ball is easy and does not require extensive input from physiotherapist [14]. This change in paralumbar spinal muscle has a positive effect on core stability and low back pain as found in a group of young athletes [15].

Bogduk (1980) described the integrated role of facet joints, multifidus and interspinous ligaments in producing what he called Lumbar Dorsal Ramus syndrome. He believed that irritation to structures innervated by the lumbar dorsal ramus may produce LBP with or without referred pain in the lower limbs, and spasm of the paraspinal, gluteal, and hamstring muscle [16]. It has been recognized for many years that the lumbar facet joints could be an important source of chronic LBP with sciatic radiation [17,18]. A recent study suggested that the multifidus muscle may be a source of local and referred pain following injecting hypertonic saline into the lumbar multifidus opposite the L5 spinous process in 15 healthy adult volunteers [19]. These findings indicate that pain relief outcomes for non-specific LBP may be improved after injecting the structures that are supplied by dorsal ramus nerve.

In this study we compared the efficacy of perifacet injection, a specifically designed gym ball exercise programme and standard physiotherapy in the treatment of non-specific LBP.

The gym ball exercise programme was designed according to the previous study by Kader et al (2008) and included a volunteer being seated on the ball in a neutral position and being guided through a series of flexion and extension movement of the spine. The feet were kept on the ground firmly [14].

MATERIAL AND METHODS

This randomised controlled trial was approved by the local ethical committee. Clinical information was obtained according to the study protocol. Magnetic resonance imaging (MRI) was performed on seventy-two patients to confirm that there was no significant pathology in the lumbar spine and to identify the status of the multifidus muscle. Sixty-three patients (aged 23-67) with non-specific chronic LBP were recruited. The MRI scans were reviewed by a Senior Research Fellow and a designated Consultant Radiologist. Patients with LBP, with or without leg pain and MR images showing multifidus muscle degeneration without other significant abnormalities in the lumbar spine were then randomised using sealed envelopes to one of three treatment groups. The randomisation process was not stratified.

Inclusion criteria

Patients (aged 18-65 years) with diffuse lateralized unilateral or bilateral LBP more than leg pain for more than 3 months. Leg pain could be radiating below or above the knee. Paraspinal tenderness may be present.

Multifidus muscle atrophy in the MRI scan with no other abnormality to account for the symptoms [20]. However, patients with mild disc degeneration or dehydration (black discs) were not excluded.

Exclusion criteria

Patients with clear signs of root pain or other pathology of the lumbar spine other than myofascial, facet or ligament injuries.

Pregnancy, scoliosis, neuromuscular disease of the trunk, malignancy, fracture and previous surgery.

Symptomatic spinal stenosis, disc herniation and spondylolisthesis on the MRI scan.

- Twenty patients were randomised to one of 3 groups:
- Back education and standard physiotherapy (group A, n=20)
- Back education and gym ball exercise (group B, n=22)

- Perifacet corticosteroid injection (group C, n=21) Seven patients did not complete the trial:
- One person in group C moved from the area
- Two (A&B) could not attend the rehabilitation program due to family commitments
- Two (A&C) did not provide sufficient information
- Two were randomised (A&B) before MRI imaging; one of them had discitis and the other had severe disc degeneration in the lumbar spine

MRI imaging protocol

The magnetic resonance images were obtained using a 0.2 Tesla resistive open imaging system (Magnetom Open Viva, Siemens, Erlangen, Germany). The MR protocol included two Fast Spin Echo sequences with different T₂ weighting. Images were obtained in the sagittal and axial planes. In the sagittal plane, the following parameters were used: TR 4000 / TE 134 with an echo train of 15, section thickness 5 mm, FOV 350 mm, and 2 signals were averaged. In the axial plane, a TR 3000 / TE 106 with an echo train of 5, section thickness 5mm, 250 mm FOV was used, averaging 4 signals.

Physiotherapy programs

Details of the physiotherapy programs are shown in Table I.

The three treatment groups

A – Back education and standard physiotherapy

This program involved a combination of educational sessions and exercise interventions. Patients were seen 2-3 times per week (depending on their progress) for 10 weeks and were advised to exercise at home. The treatment was provided by a senior physiotherapist on a one to one basis. Details of the educational sessions and physical therapy programs are listed in Table 1. The patients were advised to walk, swim and remain as active as possible.

This program also involved a combination of educational sessions and exercise interventions Table I. Patients were seen 2-3 times per week (depending on their progress) for 10 weeks and were advised to exercise on the gym ball at home. The treatment was provided by a senior physiotherapist (a different one to the control group) on a one-to-one basis.

The exercise program in this group involved intense use of a gym ball in the clinic and at home. It was structured and paced to each patient's ability. Each class started with 5-10 minutes warm-up followed by gym ball exercise which involved flexion and extension of the lumbar spine and the pelvis. C – Perifacet injection (multifidus injection)

Under image intensifier control the perifacet regions at L4/5 and L5/S1 levels were injected with methylprednisolone 80 mg (Depo-Medrone) and Bupivicaine 1-2 mls of 0.5% (Marcain) bilaterally by a designated radiologist. The importance of mobility exercises such as walking and cycling was emphasised after the injection and advised at least three times weekly. They were reassessed at 10 weeks.

Outcome measures

The outcome measure questionnaires were completed by the patients immediately after recruitment and just after the treatment program finished (10 weeks). The Oswestry Disability Index (ODI) (21), SF-36 (version 1), modified Zung Depression Index, Modified Somatic Perception Questionnaire (MSPQ) and McGill Pain Questionnaire (MPQ) were used for outcome assessment.

Distress and Risk Assessment Method (DRAM)

The Distress and Risk Assessment Method (DRAM) is derived from a simple set of scales validated for use with LBP patients. It offers a simple classification of patients into those showing no psychological distress, those at risk of developing major psychological overlay, and those clearly distressed (22). The modified Zung depression index and the MSPQ are used to determine the DRAM category as follows:

- Type N (normal): modified Zung < 17
- Type R (at risk): modified Zung 17-33 and MSPQ < 12
- Type DD (distressed-depressive): modified Zung > 33
- Type DS (distressed-somatic): modified Zung 17-33 and MSPQ > 12

SF-36

The SF-36 assesses eight health concepts:

- 1) Limitations in physical activities because of health problems (PF)
- 2) Limitations in social activities because of physical/emotional problems (SF)
- 3) Limitations in usual role activities because of physical health problems (RP)
- 4) Bodily pain (BP)
- 5) General mental health (psychological distress and well-being) (MH)
- 6) Limitations in usual role activities because of emotional problems (RE)
- 7) Vitality (energy and fatigue) (VT)
- 8) General health perceptions (GH)

Tab. 1. Details of the physiotherapy programs

Back education and gym ball exercise	Back education and standard physiotherapy		
10 week programme:	10 week programme:		
· Pain talk	· Pain talk		
· Ergonomics	· Ergonomics		
· Goal setting	· Goal setting		
Anatomy	· Anatomy		
Warm up 5-10 mins on bike	Warm up 5-10 mins on bike		
Exercise component:	Pain relief:		
· Gym ball and stretches	· Heat/ice		
	· Ultrasound/ Interferential/Curopulse		
Class x 2 week – 45 minutes	· Mobilisations		
· Neutral sit – stability			
+ Weights and legs/arms	Mobility:		
· Pelvic tilting (flex/ext)	· McKenzie		
 Side gliding with overstretch 	· Maitland		
· Full forward flexion	· Mulligan		
· Full extension if necessary			
· Full circles			
· Bouncing on ball	Stability:		
a	• Transversus/multifidus – without the use of gym ball		
Stretches:	TT ' 1'1		
· Iliopsoas, Hamstring, Quadriceps	Home exercise programme – daily		
Iliotibial band, Piriformis, Gluteus	• Swimming/walking daily (20 mins)		
Hip adductors and abductors			
· Pelvic rocking and tilting			
Home exercise programme:			
\cdot 30 mins per day on the gym ball			
· Swimming/walking daily (20 mins)			

An overall physical component score (PCS) and mental component score (MCS) may then be derived from the above scales.

McGill Pain Questionnaire

The McGill Pain Questionnaire (MPQ) consists primarily of three major descriptors—sensory, affective and evaluative. It also contains an intensity scale and other items to determine the properties of pain experience [23].

Various measures can be derived from the questionnaire. The three major measures are:

- 1) the Pain Rating Index (PRI), based on two types of numerical values that can be assigned to each word descriptor
- 2) the number of words chosen
- the Present Pain Intensity (PPI) based on a 1-5 intensity scale and 0 for no pain

In this project the Present Pain Intensity (part three of the MPQ) and Pain Rating Index (part one of the MPQ), based on the rank values of the words, were used. The values of the words chosen by the patients were then added up to obtain a score for each category, and a total score for all categories [23].

Analgesic intake

The type and the frequency of analgesic intake were recorded in this study.

Statistical methods

Analysis of variance was used to test whether the mean change scores in each group were the same. Two analyses were performed for each outcome measure: one based on the final scores and one based on the change in the scores from baseline. In each case the analysis of variance was used to test the null hypothesis that the true mean in each of the three groups was the same. Pair wise differences between treatment groups were examined using Tukey's adjustment for multiple comparisons.

RESULTS

The three groups were similar at trial entry. 56 patients (29 male and 27 female) completed both sets of questionnaires. The mean differences in the various outcomes before and after intervention are listed in Table 2. It can be seen that after standard physio-therapy there was relatively little difference in the mean scores at follow-up when compared with base-line. There tended to be larger changes in the mean

	Scores at baseline				Scores at follow -up		
	Standard physio	Multifidus muscle Rehab	Perifacet injection with steroid	Standard physio	Multifidus muscle Rehab	Perifacet injection with steroid	
Oswestry Dis Inde	ex 28.2(12.8)	32.4(19.0)	28.7(16.1)	27.4(12.1)	26.6(19.2)	23.9(14.6)	
MSPQ	5.90(4.35)	6.23(5.63)	5.55(4.11)	5.94(4.69)	4.48(5.13)	5.03(3.81)	
Modified Zung	20.4(8.1)	20.3(12.1)	23.3(11.1)	19.6(8.6)	16.9(12.2)	24.0(11.1)	
EQ-5D utility	0.60(0.27)	0.59(0.32)	0.43(0.33)	0.70(0.18)	0.66(0.32)	0.68(0.19)	
SF-36 PF	59.7(21.0)	53.3(24.2)	58.2(23.3)	63.7(19.2)	64.1(26.6)	63.7(25.4)	
SF-36 SF	72.1(24.4)	64.4(34.0)	71.1(24.7)	66.9(27.6)	77.5(29.7)	70.4(31.0)	
SF-36 RP	25.0(34.2)	30.0(38.6)	39.5(45.9)	26.6(40.3)	53.9(42.7)	52.6(47.1)	
SF-36 RE	51.0(44.3)	71.7(39.4)	59.6(43.9)	64.6(43.0)	75.0(35.7)	73.7(42.4)	
SF-36 MH	69.9(14.4)	72.8(16.9)	67.6(19.2)	68.7(12.9)	76.4(15.2)	68.2(20.8)	
SF-36 VT	50.9(13.1)	47.5(24.0)	42.9(21.9)	50.9(19.5)	55.8(21.7)	53.4(23.9)	
SF-36 BP	42.2(15.9)	39.5(20.7)	33.5(17.3)	40.4(18.7)	49.4(26.9)	54.8(25.4)	
SF-36 GH	58.4(22.8)	56.2(24.3)	57.4(21.2)	59.2(20.1)	60.3(24.1)	62.4(21.9)	
SF-36 PCS	35.6(8.8)	32.7(10.9)	35.2(8.1)	34.8(7.9)	38.3(11.5)	40.4(11.6)	
SF-36 MCS	48.2(9.5)	51.0(10.3)	47.7(10.4)	50.1(10.4)	52.6(9.8)	48.8(12.0)	
MPQ	23.4(16.4)	19.1(13.5)	22.7(14.8)	23.0(15.1)	12.2(11.5)	15.4(10.6)	

Tab. 2. Outcomes of the three treatment groups after intervention

scores in the other two groups. Standard physiotherapy did not change any of the outcome measures significantly. While the gym ball exercise program improved SF-36 physical functioning, social functioning, reported health transition and physical capacity summary scores and perifacet injections improved SF-36 bodily pain and reported health transition significantly.

The Oswestry Disability Index improved in general from a mean of 29.9 to 25.9. The mean improvements in the ODI were -0.8, -5.8 and -4.8 after standard physiotherapy, gym ball exercise program and perifacet injection, respectively. Although the gym ball exercise and the injection groups tended to improve the most, there was no evidence, however, of statistically significant differences between the groups.

There were no statistically significant differences between groups in either the modified Zung depression index (P=0.72) and the Modified Somatic Perception Questionnaire (P=0.30). However, it is interesting to see a potentially clinically significant change from 20.3 to 16.9 in the mean modified Zung depression score in the gym ball exercise group, whereas there was a slight worsening of the score in the perifacet injection group after treatment and minimal improvement in the score after standard physiotherapy.

The DRAM outcome measure showed that 62% of the patients in this study were either at risk from developing psychological overlay or were already distressed. However there was no significance differ-

ence in DRAM scores among the patients in the three treatment groups (P=0.72).

There were statistically significant differences in the change in the SF-36 bodily pain score (P=0.04) between groups. The largest improvement was in group C (Perifacet injection) (mean improvement 21.2 (95% CI 2.1 to 44.0), with a mean improvement in group B (gym ball exercise program) of 9.9 units. Group A (standard physiotherapy program) had the worst mean score after treatment.

SF-36 social functioning scores improved the most in group B (gym ball exercise program) (P=0.03). There were no other statistically significant differences between groups for any of the other SF-36 subscales. The overall physical component summary (PCS) improved by a similar amount in groups B and C but worsened slightly in the standard physiotherapy group (P=0.07). There were no differences between groups in the mental component summary (MCS) score (P= 0.09).

The McGill Pain Rating Index improved by 0.4, 6.8 and 7.2 points in groups A, B and C, respectively. Although this clearly shows a trend towards greater improvement in groups B and C, there were no statistically significant differences between groups. However, the Present Pain Intensity score of MPQ showed a significant decrease in pain intensity in group C.

It was also noted that the amount of daily analgesia had been cut down or stopped by the end of the intervention in the majority of the patients who had

Tab. 3. Number of patients taking analgesia daily, before and after treatment

Groups	Total number	Unknown	Before intervention —	After intervention		
	i otai number			Cut down	Stopped	Continued
A : Standard	17	1	14/16	5	3	6
B : Gym ball	20	2	17/18	7	6	4
C : Perifacet injection	19	1	16/18	2	2	12

physiotherapy when compared with perifacet injection (Table 3). Four patients did not answer the question. Keeping in mind that some did not take analgesia before intervention, hence 14/16.

DISCUSSION

It has been shown that perifacet injection may be more effective than physiotherapy alone in relieving LBP and improving general health. However, back education and the gym ball exercise program appeared to improve the functional status of the patients without having a significant effect on pain level.

This randomised controlled trial was designed on the basis that multifidus muscle atrophy can be diagnosed using MRI and the specific exercises tested can improve the outcome of low back pain [24]. Among other core stability exercises, gym ball exercise is widely used by physiotherapists, but the clinical effectiveness of such an exercise is not well studied in the literature [25]. The gym ball exercises described in this have previously been shown to increase the water content of the paralumbar spinal muscle [14].

Although the mean score in the Oswestry Disability Index improved overall from 29.9 to 25.9, there was no evidence of statistically significant differences between the groups. This may be due to the fact that the disability associated with myofascial pain is minor. It is well known that the ODI is better in assessing severe degrees of disability such as the failed back surgery syndrome and less sensitive to minor changes in mild disability [26]. The other possible cause is that the number of the patients in each group was not big enough to eliminate type II error and detect clinically important differences.

The Distress and Risk Assessment Method offers a simple classification of patients into those showing no psychological distress, those at risk of developing major psychological overlay, and those clearly distressed [22]. 62% of the patients in this study were either at risk from developing major psychological overlay or were already distressed. This is consistent with the previously published work which regards patients with emotional disturbance as being more prone to myofascial dysfunction [27].

The SF-36 as a measure of successful treatment for low back pain has been demonstrated and validated [28]. Using all eight scales of the SF 36 questionnaire showed high reliability when used to monitor health in groups of patients across a diverse population, and at least four scales possess adequate reliability for use in managing individual patients [29,30].

Although the bodily pain section of SF-36 showed evidence that the greatest improvement was in the perifacet injection group (group C), the McGill Pain Rating Index (PRI) did not show any significant differences in pain between the groups. However, once again the improvements in the Back education and gym ball exercise group (Group B) and Perifacet injection group (Group C) were much larger than for the standard physiotherapy group and the trial may not have been large enough to detect differences between groups. The Pain Rating Index improved by 36% (PRI=19.1 pre to 12.2 post) in the group who completed the gvm ball rehabilitation program and by 32% (PRI=22.7 pre to 15.4 post) in the perifacet injection group, but only minimally in the standard physiotherapy group (PRI=23.4 pre to 23.0 post).

This finding may be correlated with the recommendation made from European Guidelines for the management of non-specific chronic low back pain. The guideline indicates that physiotherapy and exercise is superior to General Practitioner (GP) care for reduction of pain and disability at least at mid-term period (3-6) months. Supervised physiotherapy has been recommended as first line treatment for nonspecific chronic low back pain [31]. The mean pain reduction by about a third in the gym ball exercise and perifacet injection groups would be regarded as a clinically significant improvement although they were not statistically significant. The Present Pain Intensity (PPI) score, which is another measure of pain in the McGill questionnaire, showed significant differences with the biggest improvement in the perifacet injection group. Pain scales such as Present Pain Intensity, which is a general evaluative category of sensory and affective dimensions of pain, may be used by the patient as an implicit communication requesting help from the physician or indicating optimism that relief may occur [23]. Melzack noticed from patients' reports that PPI fluctuates considerably as a function of psychological factor at the moment: mood, anxiety level, attention and so forth. The issue surrounding this variable rating has been raised in the past and attributed to patients' past experience, mood and expectation.

There is a good reason to anticipate reduction in self-rated pain if the muscular deficits are intricately linked with the source of pain as improvement of muscle support helps to stabilise the injured or unstable joint. However, if the decline in muscle function is simply the result of general disuse or secondary to other spinal pathologies, then muscle improvement does not necessarily lead to pain relief [32]. In this study, nearly one-third of the patients who had gym ball exercise reported pain relief. This may indicate that those patients were suffering primarily from pain related to muscle deficit.

It was, however, encouraging to discover that the amount of daily analgesia had been cut down or stopped after intervention in 13 out of 20 patients who completed gym ball exercise compared to 4 out of 19 patients in the perifacet injection group and 8 out of 17 patients in the standard physiotherapy group. It seems that the combination of a 36% reduction in the Pain Rating Index and patient education in the group who had gym ball exercise was enough to change their attitude toward pain. This is consistent with previous studies, which showed that changing patients' attitude and encouraging them to develop new skills to cope with the disabling effect of low back pain is more effective in restoring activities of daily living and social functioning than trying to achieve pain relief only [33,34,6,35].

The traditional belief is that the degree of physical pathology is directly related to pain. Such a relationship is not always true. It has been shown that the relationship between perceived low back pain and physical disability is not linear [36]. Pain can be reported in the absence of organic pathology and on the other hand patients with physical pathology can be totally symptom free [37,38]. This demonstrates the weak association between impairments and disability indicating that there are factors other than physical pathology contributing to the reports of pain [37,39,40].

The role of behavioural, cognitive, and affective factors have each been shown to have direct effects on the report of pain, adaptation, and response to treatment, as well as indirect effects by influencing the sympathetic nervous system and neurochemical factors associated with nociception [39,40]. Fordyce believed that physicians should try to identify the biopsychosocial factors involved in low back pain and should understand that pain and suffering are not always synonymous [25].

One of the main challenges that a rehabilitation study faces is to discriminate which element of the program is responsible for the change in outcome. In this study, the educational sessions were part of the two rehabilitation programs (A and B) of the trial. Patients were taught about pain and its management, anatomy, ergonomics, postures, goal setting and pacing. Patients in the perifacet injection group (C) did not have similar educational sessions during the 10 weeks of the program. However, all the patients in this group were advised after the injections, to keep active and the importance of mobility work and exercises such as walking and cycling were emphasised. This may have had an effect on the patients' functional recovery and their attitude toward consuming analgesia. This may be regarded as one of the weaknesses in the trial. However, the educational sessions did not appear to have a great impact on group A of the rehabilitation (standard physiotherapy), as it did not significantly improve either pain or physical function. Therefore it would be hard to estimate their overall impact on the trial's result.

The inclusion of advice on mobility and exercise to group C may be regarded as a limitation, as it may have blurred the distinction between this group and those which received educational sessions. Furthermore, this study covered a relatively small sample size spread over a wide range age group. The spread in age is a direct consequence of the inclusion and exclusion criteria specified, but might be regarded as a limitation.

In this study the outcome measures were assessed immediately at the end of the intervention period (3 months). This could also present a weakness to this study as evidence suggests that patients may get recurrence of symptoms within 12 months of symptom onset [41].

CONCLUSIONS

The ultimate question, critical in relation to the clinical relevance of back muscle function, is whether rehabilitation to improve the condition and physical capacity of the paraspinal muscles of back pain patients actually results in a corresponding reduction in self-rated pain and disability [19]. This paper shows the following conclusions:

With specific muscle rehabilitation exercises the patient's function can be improved.

Improvement in self-rated pain in response to rehabilitation, however, remains a contentious issue. The outcome measure questionnaires are as reliable as the person who answers the questions. Since the way people fill these forms are affected by many biopsychosocial factors, it remains to be seen if these are as reliable as researchers' claim they are

Arguably, the most accurate way to measure the true effect of an exercise on a particular muscle is by assessing muscle structure, histology and performance directly, by using MRI, muscle biopsy, ultrasound and EMG rather than relying on indirect questionnaires

Chronic Low Back Pain (CLBP) is a multidimensional clinical entity requiring multiple approaches in treatment. We are in agreement with studies showing that no single intervention alone can provide effective treatment of the overall problem of CLBP [41].

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