Epidural Steroid Injection Versus Conservative Measures in Treatment of Chronic Axial Low Back Pain, A Prospective Randomized Controlled Study

Tarek S. Shafshak, Mazen M. Fakhry, Ahmed R. Abdelfadil, Mayada F. Noaiem, and Hoda M. A. Abdel-Naby

ABSTRACT

Chronic low back pain (CLBP) is a very common disorder with various management strategies. There is still debate regarding treatment alternatives for axial CLBP. This study aimed to compare the effect of epidural steroid injection (ESI), interferential current (IFC) therapy and core strengthening exercises in a prospective randomized controlled manner. Hence, sixty patients complaining of axial CLBP were included and randomly assigned into either a group of ESI and exercises (group A) or IFC and exercises (group B) or exercises only (group C); each group was of 20 patients. Outcomes were visual analogue scale (VAS) for pain, Oswestry disability index (ODI) for function and Beck’s depression inventory (BDI) for depression, assessed at baseline and 3-, 6- and 12-week follow-ups. At the start of the study, there were no significant differences between the three groups in age, gender, cause and duration of CLBP, body mass index, abdominal muscle power, muscle spasm or tenderness (p > 0.05). Significant improvement in VAS and ODI at 3-, 6- and 12-weeks was observed compared to baseline assessment in the three studied groups. The improvement was higher for group A compared to B and C. BDI was significantly improved in group A and C at 3 weeks, and in all groups at 6- and 12-weeks compared to baseline. However, at the end of the study, there was no significant difference in the BDI between the three groups. From this study and over a period of 3 months, all studied groups showed improvement in pain, function, and depression but the group who received epidural steroid injection with core strengthening exercises was statistically better than the other two groups, with significant improvement in pain and function, but not in depression. Early effective assessment and dealing with depression, even prophylactic treatment and cognitive behavioral therapy should be addressed.

Trial registration: The Pan African Clinical Trial Registry (www.pactr.org) identification number is PACTR201901523042787 on 16 January 2019.

Keywords: Epidural injection, exercise therapy, interferential therapy, low back pain.

I. INTRODUCTION

The prevalence of chronic low back pain (CLBP; LBP persisting for ≥12 weeks) in adults had been doubled in the last decade and still increases dramatically in the aging population [1]-[3]. It is mostly caused by complex interactions of various factors; biomechanical, psychological, social and physical demands. In addition to co-morbidities like depression and anxiety, causing a complex and demanding therapeutic challenges [4], [5].

The modalities for managing CLBP continue to increase. It includes surgical interventions, conservative and interventional therapies [6]. The initial assessment is very important for reaching a diagnosis as well as for evaluation of the degree and sources of pain, and functional disability [7]. It enables the healthcare professionals to outline a management strategy according to the magnitude of the problem [1]. Still, there is no consensus for treatment present. Treatment recommendations are mostly based on trials from high-income countries [6].

The benefits of epidural injection for LBP have been recommended in numerous studies, especially those attributed to radiculopathy. Epidural injection of either local anesthetic solutions, corticosteroids, or combinations given either through inter-laminar, trans-foraminal, or caudal approaches are commonly indicated for pain relief and improvement of range of motion of the spine and function [8]. On the other hand, other studies dispute its role.

Conservative measures for CLBP include patient education, lifestyle modification, pharmacotherapy, therapeutic exercises and physical therapy.

For patients with CLBP, the recent guidelines continue to recommend strength-building exercise therapy either as a sole treatment or as a part of a multidisciplinary program of...
rehabilitation in subacute and CLBP with an added benefit of improving posture and endurance [9].

The physical therapy modalities comprise electro-analgesic current stimulation, especially transcutaneous electrical nerve stimulation (TENS) and interferential current (IFC) therapy. IFC is an alternating current of medium frequency, with an amplitude modulation at a low frequency [10]. However, the efficacy of IFC in axial lumbar pain remains controversial.

There is still debate regarding a definitive approach for managing axial CLBP; (axial pain without sciatica nor neurogenic claudication lasting for more than 12 weeks). There is still variation between practitioners in management by either conservative and/or invasive approaches. So, this study aimed to compare in a prospective controlled trial the effects of epidural steroid injection (ESI) plus core strengthening exercises versus IFC plus exercises versus exercises alone in patients with axial CLBP.

II. PATIENTS AND METHODS

This is a single center, parallel-group, controlled, non-blinded study, with balanced randomization. This study was conducted on sixty patients, aged between 22-55 years, complaining of chronic axial LBP (persisting for ≥12 weeks). Those patients were selected from those attending the Out-Patient clinic of Physical Medicine, Rheumatology and Rehabilitation, and the Out-Patient clinic of Neurosurgery, Alexandria University Hospitals. All patients were instructed to stop taking any analgesics at least 3 days prior to their participation and until the end of the study. Patients were excluded from the study if they had any of the following: BMI > 35, poor abdominal muscle power, spinal nerve root compression presenting with sciatica, spinal canal stenosis, multiple level disc prolapse, spondylolisthesis, previous spinal surgery, pre-existing neurologic deficits, psychiatric illnesses, polyneuropathy, systemic arthropathy, generalized pain or any associated regional pain.

All patients were subjected to the following:
(1) Through history taking and clinical examination.
(2) Plain radiographs and MRI of lumbosacral spine.
(3) Evaluation of pain using the visual analogue scale (VAS) [11], of functional capacity using the Oswestry disability index (ODI) [12] and evaluation of depression using the Arabic version of Beck's depression inventory (BDI) [13], [14].

The patients included in the study were aware of the side effects and probable complications. Written informed consent was obtained from all participants. The study was approved by the Alexandria Medical Ethical Committee.

Participants were randomly assigned following simple randomization procedures (computerized random numbers) to 1 of 3 treatment groups (A, B, or C); each group was of 20 patients. The details of the statistical series were unknown to any of the investigators and were kept by an independent physiatrist not involved in the research. After the main investigator had obtained the patient's consent, she telephoned the physiatrist who was independent of the recruitment process for allocation consignment. Blinding was not feasible in the current study.

Group A received one blind inter-laminar epidural corticosteroid injection of triamcinolone acetonide 40 mg diluted in normal saline to a total volume of 10 ml in the corresponding lumbar interspace using midline approach with 18-gauge needle in the prone position [15]. This procedure was carried out in the operating theater under complete aseptic precautions by the same physician. After that, isometric core strengthening exercises for the back and abdominal muscles were received four times per week for three successive weeks (total of 12 exercise sessions).

Patients of group B received IFC therapy; two-pole technique, amplitude modulation (Endomed 482, Enraf-Nonius BV, Rotterdam, The Netherlands) for 20 minutes; besides isometric core strengthening exercises for the back and abdominal muscles; four sessions per week for three successive weeks (total of 12 sessions).

Patients of group C received only isometric core strengthening exercises for the back and abdominal muscles four times per week for three successive weeks (total of 12 exercise sessions).

Regarding exercise program; all participants were instructed to maintain a neutral spinal position through isometric contractions of the lumbar multifidi and transversus abdominis. Static lumbar stability exercises were started with curl-up, pelvic bridge, side bridge, and quadruped positions. The intensity of exercises for each participant was controlled based on the exercise tolerance and pain thresholds. Patients were supervised in the Department of Physical Medicine, Rheumatology and Rehabilitation. Exercises were conducted for 3 successive weeks; four times per week.

A. Statistical Analysis of the Data

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0 (Armonk, NY: IBM Corporation). Qualitative data were described using numbers and percentages. The Kolmogorov-Smirnov test was used to verify the normality of distribution. Quantitative data were described using means and standard deviations. The significance of the obtained results was judged at the 5% level [16], [17]. Chi-square test was used for categorical variables, to compare between different groups and Fisher's Exact was used when more than 20% of the cells have expected count less than 5. F-test (ANOVA) was used for normally distributed quantitative variables, to compare between more than two groups, while ANOVA with repeated measures was used to compare between more than two periods or stages. For abnormally distributed quantitative variables; Kruskal Wallis test was used, to compare between more than two studied groups and Friedman test to compare between more than two periods or stages. Post Hoc test was used for pairwise comparisons.

Sample size was calculated using G-Power 3 software, based on expected difference in pain and function outcomes in the studied groups [2]. To achieve power of 80% at 95% confidence level, the minimum accepted sample size was 11 patients per group with a total of 33 patients.
There were 41 females (68.3%) and 19 male patients with chronic axial LBP. There were 41 females (68.3%) and 19 male patients with chronic axial LBP. There were 41 females (68.3%) and 19 male patients with chronic axial LBP. There were 41 females (68.3%) and 19 male patients with chronic axial LBP. There were 41 females (68.3%) and 19 male patients with chronic axial LBP. There were 41 females (68.3%) and 19 male patients with chronic axial LBP.

### TABLE I: CLINICAL CHARACTERISTICS OF THE THREE STUDIED GROUPS

| Characteristics               | Group A (n=20) | Group B (n=20) | Group C (n=20) | Test of significance | P |
|-------------------------------|----------------|----------------|----------------|----------------------|---|
| Age (years)                  | 40.8 ± 9.7     | 41.4 ± 8.1     | 37.9 ± 5.7     | F=1.064              | 0.352 |
| Gender (F:M)                 | 13:7           | 13:7           | 15:5           |                      | 0.735 |
| Pain duration (years)        | 1.9 ± 1.3      | 2.5 ± 2.3      | 2.05 ± 1.1     | H=0.288              | 0.352 |
| Weight (kg)                  | 82.6 ± 8.83    | 80.4 ± 8      | 78.1 ± 10.4    | F=1.23               | 0.298 |
| BMI (kg/m²)                  | 31 ± 2.8       | 30.1 ± 3.5     | 29.5 ± 4.2     | F=0.358              | 0.390 |

F: M female to male ratio; χ²: Chi square test; F: ANOVA test; H: Kruskal Wallis test; p: p value for comparing between the three groups

### TABLE II: COMPARISON OF THE OUTCOME VARIABLES AT THE FOUR PERIODS OF ASSESSMENT IN EACH GROUP (INTRAGROUP COMPARISON)

| Characteristics | Initial | 3 weeks | 6 weeks | 12 weeks | Test of significance | P |
|-----------------|---------|---------|---------|----------|----------------------|---|
| VAS             | 6.25 ± 1 | 2.6 ± 1.18 | 2.4 ± 0.99 | 2.4 ± 1.15 | F=53.2*              | <0.001* |
|                  | Group A |         |         |          |                      |   |
|                  | p<0.001 |         |         |          |                      |   |
|                  | Group B | 6 ± 0.97 | 4.1 ± 1.73 | 3.9 ± 1.79 | 3.9 ± 1.85 | F=41.0*              | <0.001* |
|                  | p<0.001 |         |         |          |                      |   |
|                  | Group C | 5.7 ± 0.6 | 3.8 ± 1.09 | 3.7 ± 1.13 | 3.6 ± 1.04 | F=50.1*              | <0.001* |
|                  | p<0.001 |         |         |          |                      |   |
|                  | Group A | 24 ± 7.15 | 11.6 ± 5 | 11.1 ± 4.3 | 11.2 ± 4.2 | F=80.1*              | <0.001* |
|                  | p<0.001 |         |         |          |                      |   |
|                  | Group B | 25.5 ± 6.7 | 19.9 ± 7.2 | 19.6 ± 7.4 | 19.7 ± 7.5 | F=28.428*            | <0.001* |
|                  | p<0.001 |         |         |          |                      |   |
|                  | Group C | 21.2 ± 4.9 | 15.9 ± 4  | 15.4 ± 4  | 14. ± 4.18 | F=44.235*            | <0.001* |
|                  | p<0.001 |         |         |          |                      |   |
|                  | Group A | 6.3 ± 3.13 | 5.4 ± 2.14 | 5.2 ± 1.91 | 5.1 ± 1.87 | F=20.886*            | <0.001* |
|                  | p<0.001 |         |         |          |                      |   |
|                  | Group B | 6.9 ± 5.21 | 6 ± 3.86 | 5.6 ± 3.5 | 5.6 ± 3.50 | F=24.729*            | <0.001* |
|                  | p<0.001 |         |         |          |                      |   |
|                  | Group C | 7.2 ± 4.5 | 6.1 ± 3.24 | 5.9 ± 2.9 | 5.9 ± 2.88 | F=25.897*            | <0.001* |
|                  | p<0.001 |         |         |          |                      |   |

F: F test (ANOVA) with repeated measures; χ²: Chi square; Fr: Friedman test. Significance: between periods was done using Post Hoc Test (Dunn’s); p: p value for comparing between the four periods in each group; p1: p value for comparing between baseline and different periods in each group; *: Statistically significant at p ≤ 0.05

### TABLE III: COMPARISON BETWEEN THE THREE STUDIED GROUPS ACCORDING TO THE OUTCOME VARIABLES (INTERGROUP COMPARISON)

| Characteristics | Group A (n=20) | Group B (n=20) | Group C (n=20) | Test of significance | P |
|-----------------|----------------|----------------|----------------|----------------------|---|
| VAS             | 6.2 ± 1.07     | 6 ± 0.97       | 5.8 ± 0.83     | H= 1.879             | 0.391 |
|                  | 2.6 ± 1.18     | 4.1 ± 1.73     | 4 ± 0.86       | H= 12.978*           | 0.002* |
|                  | 2.4 ± 0.99     | 3.9 ± 1.79     | 3.7 ± 0.91     | H= 14.064*           | 0.001* |
|                  | 2.4 ± 1.15     | 3.9 ± 1.85     | 3.7 ± 0.91     | H= 12.262*           | 0.002* |
|                  | 61.5 ± 15.6%   | 36 ± 23.6%     | 35 ± 13.6%     | H= 22.273*           | <0.001* |
| % of Improvement | 6.3 ± 1.18     | 6.95 ± 5.21    | 7.2 ± 4.53     | H= 0.404             | 0.817 |
|                  | 5.4 ± 2.14     | 6 ± 3.86       | 6.1 ± 3.24     | H= 0.503             | 0.778 |
|                  | 5.2 ± 1.91     | 5.65 ± 3.5     | 5.9 ± 2.89     | H= 1.074             | 0.584 |
|                  | 5.1 ± 1.87     | 5.6 ± 3.50     | 5.9 ± 2.88     | H= 1.162             | 0.559 |
|                  | 52.3 ± 16.2%   | 25.9 ± 17.3%   | 29.2 ± 15.8%   | H= 24.021*           | <0.001* |
| % of Improvement | 6.3 ± 3.13     | 6.95 ± 5.21    | 7.2 ± 4.53     | H= 0.404             | 0.817 |
|                  | 5.4 ± 2.14     | 6 ± 3.86       | 6.1 ± 3.24     | H= 0.503             | 0.778 |
|                  | 5.2 ± 1.91     | 5.65 ± 3.5     | 5.9 ± 2.89     | H= 1.074             | 0.584 |
|                  | 5.1 ± 1.87     | 5.6 ± 3.50     | 5.9 ± 2.88     | H= 1.162             | 0.559 |
|                  | 52.3 ± 16.2%   | 25.9 ± 17.3%   | 29.2 ± 15.8%   | H= 24.021*           | <0.001* |
| % of Improvement | 14.6 ± 12.4    | 13.79 ± 17.2   | 12.3 ± 15.4    | H= 0.758             | 0.684 |

F: F for the ANOVA test, pairwise comparison between each 2 groups was done using the Post Hoc Test (Tukey); H: H for Kruskal Wallis test; p1: p value for comparing between groups A and B; p2: p value for comparing between groups A and C; *: Statistically significant at p ≤ 0.05

### III. RESULTS

#### A. Baseline Characteristics

This study was carried out on 60 patients with chronic axial LBP. There were 41 females (68.3%) and 19 male patients (31.6%); their ages ranged between 22 and 55 years old. All of the 60 patients had completed the treatment plan and assessments.

There was no statistically significant difference between the three studied groups regarding age, gender, pain duration, the cause of pain, body weight, body mass index (BMI),...
abdominal muscle power, muscle spasm or tenderness. The most common cause of axial LBP in the three studied groups was lumbar spondylolisthesis. (29 patients = 48.3%). (Table I)

B. Analysis of Outcomes

1) VAS for Pain

There was a significant improvement in VAS at 3 weeks, 6 weeks and 12 weeks when compared with pretreatment VAS in the three studied groups (intragroup comparison). The percent of improvement in VAS at the end of the study in group A was significant compared to either group B or group C (Table II, III).

2) Functional capacity

There was a significant improvement in ODI at 3 weeks, 6 weeks and 12 weeks when compared with pretreatment ODI in the three studied groups (intragroup comparison). There was a significant difference in ODI improvement between group A compared to either group B or C at the end of the study (Table II, III).

3) Depression

There was a significant improvement in BDI at 3 weeks, 6 weeks and 12 weeks when compared to baseline assessment in the three studied groups except at 3 weeks in group B (intragroup comparison). However, on doing intergroup comparison, that difference did not reach statistical significance between the three studied groups at all assessment periods (Table II, III).

C. Adverse Events

No major adverse events were reported in either group.

IV. DISCUSSION

Chronic LBP is a common health problem with a strong societal impact. Its prevalence increases linearly from the third decade of life on, until 60 years of age [18]. All patients in this study were in a similar age group as their ages ranged from 22 to 55 years, with a mean of 38.8 years. It has been reported that women have a higher incidence of LBP than men [1]. A similar observation was found in this study, where 68.3% of the participants were females and 31.67% were males. In contrast to these findings, [3] revealed the prevalence of LBP among males 57.3% more than females 42.7%.

Despite the availability of multiple treatment modalities for chronic LBP, one can't decide on the best treatment regimen owing to lack of sufficient data from placebo-controlled trials and prospective randomized trials for patients with axial LBP and lack of direct comparative studies [19]. Different conclusions have been reached about the efficacy of epidural injections versus various physiotherapy modalities (as one of the conservative measures) in managing chronic axial LBP; this may be due to the diversity of physical therapy methods, which makes it difficult to compare between their results. Also, most of the comparative studies were for radicular chronic LBP.

So, in this prospective randomized controlled study we compared the effect of ESI plus therapeutic exercises versus IFC plus therapeutic exercises versus therapeutic exercises alone in the treatment of chronic axial LBP.

It was important for us to determine the improvement from baseline to follow-up periods in each group (intragroup comparison) in line with the intergroup comparison.

In our study, we used pain, function, and depression as outcome measures; most of the comparative studies use only pain and function as outcome measures. We used depression as it is a common comorbidity for those complaining of chronic LBP. Regarding pain and function (VAS, ODI); there was an improvement in all post-treatment assessments when compared to pretreatment within each group (intragroup comparison). However, the improvement was better in group A when compared to either group B or group C (intergroup comparison).

Soliman [20] studied the efficacy of epidural injection versus other conservative measures (medications, physical therapy, and rehabilitation measures) in patients with lumbar disc herniation. All groups showed improvement in pain and function, confirmed by a decrease in the mean VAS and ODI scores, but groups of injection showed a significant difference when compared with the group of conservative measures. Similarly, [21] demonstrated the same findings regarding VAS and ODI (in a total of 99 patients with chronic LBP; 52 received physiotherapy and 47 received epidural neuroplasty). Although the data concluded from both studies are in accordance with ours, both studies were done for radicular LBP, didn't differentiate forms of the conservative measures and used different techniques for ESI.

Regarding management of axial LBP, [22] concluded that lumbar inter-laminar epidural injections of local anesthetic with or without steroids are effective in patients with chronic axial LBP.

Also, [23] compared the effect of epidural injection (ultrasound-guided caudal epidural injection of 40 mg methylprednisolone with 2 ml of 2% lidocaine and 20 ml of 9% normal saline; two injections with one-week interval) in treatment of patients with chronic discogenic LBP with or without radicular pain versus conservative treatment with pulsed electromagnetic field stimulation. Both groups followed an exercise program. Highly significant improvement in pain and functional status was recorded in both treatment groups, with an insignificant difference in between.

A retrospective study, done by [24], compared minimal invasive techniques and physiotherapy in elderly patients with LBP, demonstrated no superiority of either treatment in pain and functional status. These results contradict our findings but this could be attributed to, different age group of selected patients’ groups, and the different design of the study. Also, [25] in 2009 demonstrated no difference between ESI and physiotherapy.

There was some improvement in BDI following treatment (intragroup comparison) in each group. However, there was no statistical difference between the three studied groups at all assessment periods (intragroup comparison).

A meta-analysis done by [26], expected that low mood and depressive symptoms led to lower odds of returning to work at follow-up (whatever treatment received) and decreased persons’ expectation and ability to foresee recovery.

There were a number of potential limitations in our study, as there was no fluoroscopy or ultrasound guidance during...
ESI as blinded injection is the most implemented technique in our country. Also, a single injection was done, although some studies recommended three injections for more efficacy, whereas others suggested that only one injection could be effective with lower side effects and additional injections can only be supplemented either on patient demand, or on exceeding a preset patient’s pain level. The exercise program included only a strengthening program, but there is still variation in the most effective program.

V. CONCLUSION

Over a period of 3 months, all studied groups showed improvement in pain, function, and depression, but the group of ESI plus exercise was statistically better, with significant improvement in pain and function, but not in depression.

We recommend that no individual treatment should be prioritized and management plans should be individualized; practitioners should not only consider efficacy but other factors should be taken into account, such as safety, reproducibility, treatment cost, patient preferences, and compliance. Also, early effective assessment and dealing with depression, even prophylactic treatment and cognitive behavioral therapy should be addressed. Further studies are recommended with a larger number of patients and a long period of assessment to estimate the sustainability of remission and if either ESI or conservative measures would delay or offset the need for surgery.

ACKNOWLEDGMENT

Thanks to all patients who have participated in and completed this study.

CONFLICT OF INTEREST

Authors declare that they do not have any conflict of interest.

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