Comparison of surgical or nonsurgical treatment outcomes in patients with thoracolumbar fracture with Score 4 of TLICS

A randomized, single-blind, and single-central clinical trial
Alireza Mohamadi, MD, Ali Googanian, MD, Ali Ahmadi, MD, Alireza Kamali, MD

Abstract
Background: Thoracolumbar fractures are among the most common types of damages caused to the spinal cord. Therefore, the aim of this study was the comparison of surgical or nonsurgical treatment outcomes in patients with thoracolumbar fracture with score 4 of the thoracolumbar injury classification and severity (TLICS)

Methods: This study was clinical trial and double blind. Patients with thoracolumbar fracture with score 4 of TLICS entered at this research. We divided patients in 2 groups randomly (each group 25 patients) and then we followed patients for 1 year after start of treatment. We checked duration of bedridden and absence work, pain every 3 months for 1 year and radiography every 3 months for 1 year.

Results: Pain in operative group was lower than nonoperative group (P = 0.02). Regional sagittal angles (RSA) in operative group was lower than nonoperative group in all time (P = .0001). Mean of time of return to work in operative group was lower than nonoperative group (P = .001).

Conclusions: Pain and mean of time of return to work and RSA in operative group was lower than nonoperative group. The present data suggest the use of operative method in patients with thoracolumbar fracture with score 4 of TLICS.

Abbreviations: LSA = local sagittal angles, RSA = regional sagittal angles, TLICS = thoracolumbar injury classification and severity, VAS = vertebra and visual analog scale.

Keywords: fractures, lumbar, nonoperative, operative, thoracic

1. Introduction
Thoracolumbar fractures are among the most common types of damages caused to the spinal cord.[1,2] These damages are mostly the results of traumas caused by vehicle accidents and falling from heights.[1,3,4] The type and intensity of these fractures differ depending upon the type and intensity of trauma, patient’s age, body’s status during trauma, and some other factors.[4] The systematic categorizations of thoracolumbar fractures are used to diagnose and deal with these fractures in an appropriate manner.

Thoracolumbar injury classification and severity (TLICS) is currently used frequently by doctors and radiologists in order to categorize thoracolumbar fractures to devise an appropriate therapeutic strategy.[5] Based on previous evidences, the current system of categorization has an appropriate level of reliability and validity to classify thoracolumbar fractures and take appropriate therapeutic measures against them.[5,6] The following 4 parameters are used to categorize thoracolumbar fractures: morphology, neurological status, spinal cord/conus medullaris injury, and posterior ligamentous complex. Morphology is used to determine type of fracture, while other factors are utilized to diagnose existence of fracture and its level. Based on each patient’s conditions and the diagnostic measures taken, a score will be given to each item and the overall score is used to determine the proper therapeutic method for each patient. The maximum score in this classification is 10 and the following measures are defined for each score: nonoperative treatments for scores ≤ 3, operation for scores ≥ 4, and operative or nonoperative treatments for a score of 4.[7] Open fixation, internal fixation, and spondylosis as operative treatments help correct deformity, early mobilization, reduce reliability to aid devices and prevent spinal column malalignment or delayed neurological damages.[8,9] Nonoperative treatment does not suffer from the side effects of this therapeutic procedure as there are no operative interventions.[10,11]

One of the problems with this categorization is the therapeutic measure needed to deal with patients with a score of 4. Although there are many researching pointing to the fact that both operative and nonoperative treatments of patients with thoracolumbar fractures have similar clinical consequences,[12–14]
some researches show that the consequences of patients with thoracolumbar fractures undergoing operative or nonoperative treatments are different in terms of certain clinical responses.\cite{12,15} Siebenga et al.\cite{15} issued a report indicating that contrary to other clinical parameters, the frequency of post-treatment kyphosis in nonoperative group was significantly more than what was observed in operative group. The results of the research conducted by Denis\cite{12} showed that contrary to operative treatment, return to work and neurological complications were significantly more among those patients with thoracolumbar fractures undergoing nonoperative treatment. Although TLICS is an acceptable criteria for taking therapeutic measures against patients suffering from thoracolumbar fractures,\cite{5-7} some researchers believe that it is necessary to conduct further research to compare patients’ outcome in both operative and nonoperative treatments so that the classification criteria may be improved and the most appropriate clinical measure can be taken against them.\cite{5-7} Considering these explanations and shortage of proper researches on thoracolumbar fractures, the present research seeks to compare the operative and nonoperative methods.\cite{16} The present research seeks to compare the outcomes of operative or nonoperative treatments in patients suffering from moderate thoracolumbar fractures with a score of 4 in TLICS categorization.

2. Methods

2.1. Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study protocol was approved by the Ethics Committee of Arak University of Medical Sciences.

2.2. Design

This is a randomized, single-blind, and single-central clinical trial.

2.3. Population and procedures

The population includes patients suffering from thoracolumbar fractures from both sexes. The research was conducted in the neurosurgery ward of Vali Asr Hospital of Arak. A single randomized method based upon the inclusion and exclusion criteria was defined to select patients. The patients suspected of thoracolumbar complications were initially examined through a detailed representation and clinical examination. Using standard imaging (including lateral graphy and AP focused on the area suspected of fracture and CT scan and MRI), thoracolumbar fractures were confirmed in these patients.\cite{13} Utilizing TLICS categorization criteria, the patients were classified for proper therapeutic measures and, finally, only those patients who had gained a score of 4 in TLICS took part in the research. Having selected the patients and obtained their informed consent for participation in the research, the initial clinical and demographic information checklist was completed for each patient.

The following information was recorded in the checklist: age (years), gender, type of fracture (according to TLICS), neurological status (according to TLICS), spinal cord injury status (according to TLICS), posterior ligament injury status (according to TLICS), the number of fractured vertebra, and visual analog scale (VAS).

2.4. Clinical evaluation

The patients were then randomly divided into 2 groups with the first group including 25 patients undergoing operative treatment and the second group including 25 people undergoing nonoperative treatments. Nonoperative treatment included resting in the bed for at least 5 days (depending upon the pain and the unstable level of fracture), standard physiotherapy, using brace and prohibition from heavy physical activities.\cite{7,17} It is noteworthy to mention that the quality and quantity of nonoperative treatments were determined with respect to neurosurgeon’s idea and each patient’s status. Considering the type of fracture and each patient’s status, the proper operative treatment was chosen. The patients of both groups were matched in terms of trauma mechanism (accidents and falling from heights). Following the treatment, all patients were followed for 1 year. The following criteria were kept in mind while studying patients’ outcomes and following them: the length of hospitalization, length of absenteeism, returning to work prior to trauma, VAS criteria completion (this criteria was checked at the beginning of hospitalization and once every 3 months for 1 year, radiography (once every 3 months for 1 year), and VAS to measure pain levels (back pain in this case). This scale consists of a 10cm ruler ranging from 0 to 10 with 0 presenting no pain and 10 indicating intolerable pain. The patients are asked to mark their pain level in this scale. The distance from 0 to the mark made on the ruler represents pain scale.\cite{19}.

2.5. Types of outcome measures

Local sagittal angles (LSA) and regional sagittal angles (RSA) were measured to study Kyphosis deformity in the radiographies made from patients. LSA represents the angle between the upper and lower endplate of fractured vertebra. RSA shows the angle between the upper endplate of the vertebra above the fractured vertebra and the lower endplate of the vertebra under the fractured vertebra.\cite{17}.

It was the responsibility of the surgeon in charge of executing the research to diagnose fracture, select patients and prescribe operative treatment and nonoperative therapeutic recommendations and complete the checklist of patient’s demographic and clinical information before and after operation. The designated resident who was blind to type of patients and had received complete necessary trainings in this field followed and traced the patients after they were discharged from hospital. No personal or confidential information of these people was recorded. The research was thoroughly explained to the patients and they took part in the research after gaining their consent. They were free to leave the research whenever they wished. Having collected the data, they were analyzed using SPSS v.20 and statistical tests (Fig. 1).

2.6. Inclusion and exclusion criteria

2.6.1. Inclusion criteria.

II, ASAII, aging 18 to 60 years old.

Thoracolumbar fractures from T11 to L2 (without involvement of cervical vertebrae and the sacrum).\cite{15}

Less than 10 days between trauma and hospitalization.\cite{15}

Obtaining the informed consent to take part in the research.

2.6.2. Exclusion criteria:

Pregnancy, pathological, or osteoporotic failures, spinal column surgery history.
Patients with end stage disease.

Patients with ASA III and IV, patients with recent psychological records and addicted to drugs.

Considerable simultaneous traumas which may disrupt the examination of patients’ clinical responses such as considerable traumas of organs or burning.

Nonoperative management: Rest, brace, osteocalcex 6 to 8 weeks,

Operative management:

PSF (pedicular screw, rod) 2-posteriorlateral fusion with autograft and allograft

This is a single-blind, randomized clinical trial conducted on 2 groups of patients suffering from thoracolumbar fracture with a score of 4 in TLICS scale. The patients were randomly divided into operative and nonoperative groups. The patients in both groups were similar in terms of age and gender (P ≥ .05) (Table 1).

According to Table 2, a significant difference was observed between average pain score of patients suffering from thoracolumbar fractures at the beginning of the 3rd, 6th, 9th, and 12th month following the operation was observed between the 2 therapeutic groups (Fig. 2). The pain score observed in operative treatment group was less than what was observed in the other group (according to P-value calculated).

A significant difference was observed between average pain score of patients suffering from thoracolumbar fractures while being discharged from hospital between the 2 therapeutic groups. VAS score of patients suffering from thoracolumbar fracture 3, 6, 9, and 12 months following operation in both groups.

No significant difference was observed between average lengths of hospitalization of patients suffering from thoracolumbar fractures between the 2 therapeutic groups. VAS 5 vertebra and visual analog scale.

### Table 1

| Parameter                              | Points |
|----------------------------------------|--------|
| Morphology                             | 0      |
| Compression                            | 1      |
| Burst                                  | 2      |
| Translational/rotational               | 3      |
| Distraction                            | 4      |
| Neurological status                    | 0      |
| Intact                                 | 1      |
| Nerve root injury                      | 2      |
| Spinal cord/conus medullaris injury    | 2      |
| Complete                               | 3      |
| Incomplete                             | 3      |
| Caudaquina                            | 3      |
| Posterior ligamentous complex          | 0      |
| Intact                                 | 2      |
| Indeterminate                          | 3      |

### Table 2

| Pain score/group | Nonoperative group | Operative group | P-value |
|------------------|--------------------|-----------------|---------|
| Average VAS at the onset of 3 months | 7.5 ± 2.1 | 3.1 ± 1.4 | P = .001 |
| Average VAS at the onset of 6 months | 5.8 ± 1.8 | 2.4 ± 1.7 | Significant |
| Average VAS at the onset of 9 months | 4.1 ± 1.6 | 1.5 ± 1.2 | Significant |
| Average VAS at the onset of 12 months | 2.6 ± 1.6 | 1.02 ± 1.1 | Significant |

### 3. Results

The present research is a single-blind randomized clinical trial conducted on 50 patients suffering from thoracolumbar fractures with a score of 4 in TLICS scale. The patients were randomly divided into operative and nonoperative groups. The patients in both groups were similar in terms of age and gender (P ≥ .05) (Table 1).

According to Table 2, a significant difference was observed between average pain score of patients suffering from thoracolumbar fractures at the beginning of the 3rd, 6th, 9th, and 12th month following the operation was observed between the 2 therapeutic groups (Fig. 2). The pain score observed in operative treatment group was less than what was observed in the other group (according to P-value calculated).

A significant difference was observed between average pain score of patients suffering from thoracolumbar fractures while being discharged from hospital between the 2 therapeutic groups. VAS score of patients suffering from thoracolumbar fracture 3, 6, 9, and 12 months following operation in both groups.

No significant difference was observed between average lengths of hospitalization of patients suffering from thoracolumbar fractures between the 2 therapeutic groups (P ≥ .05). The average length of hospitalization in both groups was approximately 4 days (Table 4).

According to Table 5, no significant difference was observed between LSA angle of patients suffering from thoracolumbar fractures...
fractures at all times between the 2 therapeutic groups. No difference was observed between operative and nonoperative treatment of patients suffering from thoracolumbar fracture in terms of RSA angle at various times after operation ($P \geq .05$) (Fig. 3).

According to Table 6, a significant difference was observed between RSA angle of patients suffering from thoracolumbar fractures at all times between the 2 therapeutic groups ($P = .0001$). The RSA angle among patients undergoing operative treatment was significantly less. The results of this table indicate an obvious improvement of RSA angle following operative group treatment than the nonoperative group (Fig. 4).

A significant difference was observed between average length of returning to work for patients suffering from thoracolumbar fractures between the 2 therapeutic groups ($P = .01$). The average length of returning to work in operative treatment group was shorter than what was observed in nonoperative therapeutic group (Table 7).

No significant difference was observed between average ages for patients suffering from thoracolumbar fractures between the 2 therapeutic groups ($P \geq .05$). The average age in both groups was almost 48 to 49 years (Table 8).

### 4. Discussion

The present research seeks to compare the outcomes of operative or nonoperative treatments in patients suffering from moderate thoracolumbar fractures with a score of 4 in TLICS categorization. This is a double blind, randomized clinical trial conducted on 50 patients suffering from thoracolumbar fracture with a score of 4 according to TLICS categorization. The patients were purely randomly divided into the operative and nonoperative treatment groups. No significant difference was observed among the patients with thoracolumbar fracture in terms of age between the 2 groups ($P \geq .05$). The average age in both groups was 48 to 49 years old. A significant difference was observed among the patients with thoracolumbar fracture in terms of average pain score in the 3rd, 6th, 9th, and 12th month following the operation between the 2 therapeutic groups and lower levels of pain score were reported in operative treatment group for all periods. A significant difference was observed among the patients with thoracolumbar fracture in terms of the average pain score while being discharged from hospital between therapeutic groups ($P = .02$). Lower levels of pain score were reported in operative treatment group. No significant difference was observed among the patients with thoracolumbar fracture in terms of the average length of hospitalization between both treatment groups ($P \geq .05$). The average length of hospitalization for both groups

| LSA angle score/ group  | Nonoperative group | Operative group | $P$-value |
|-------------------------|--------------------|-----------------|-----------|
| LSA before operation    | 19.1 ± 3.1         | 18.66 ± 3.1     | $P \geq .05$ Not significant |
| First three months LSA  | 16.44 ± 4.4        | 15.95 ± 4.5     | $P \geq .05$ Not significant |
| Second three months LSA | 15.33 ± 3.7        | 15.27 ± 3.7     | $P \geq .05$ Not significant |
| Third three months LSA  | 15.01 ± 2.8        | 15.10 ± 4.1     | $P \geq .05$ Not significant |
| Fourth three months LSA | 13.73 ± 3.4        | 14.47 ± 4.7     | $P \geq .05$ Not significant |

LSA=local sagittal angles.

| RSA angle score/ group  | Nonoperative group | Operative group | $P$-value |
|-------------------------|--------------------|-----------------|-----------|
| RSA before operation    | 12.6 ± 3.6         | 12.88 ± 1.8     | $P \geq .05$ Not significant |
| First three months RSA  | 13.18 ± 4.8        | 2.07 ± 1.5      | $P = .0001$ Significant |
| Second three months RSA | 13.66 ± 3.8        | 1.75 ± 1.3      | $P = .0001$ Significant |
| Third three months RSA  | 14.24 ± 4.1        | 1.70 ± 1.4      | $P = .0001$ Significant |
| Fourth three months RSA | 15.25 ± 4.9        | 1.5 ± 1.1       | $P = .0001$ Significant |

RSA=regional sagittal angles.
was approximately 4 days. No significant difference was observed among the patients with thoracolumbar fracture in terms of the LSA angle in all times studied ($P \geq .05$). A significant difference was observed among the patients with thoracolumbar fracture in terms of the RSA angle in all times studied ($P = .0001$) and the RSA angle was significantly smaller among those undergoing operative treatment. A significant difference was observed among the patients with thoracolumbar fracture in terms of returning to work between the 2 therapeutic groups ($P = .001$) and the average length of returning to work in operative treatment group was much shorter. Lower levels of pain, shorter time of returning to work and smaller RSA angles were observed in operative treatment group and this method is recommended for those patients without any neurological problems.

Bakhsheshian et al\textsuperscript{[14]} conducted a review research on nonoperative treatment of patients with consecutive thoracolumbar fractures. Of the whole 45 researches, 9 dealt with nonoperative treatment, 20 dealt with both operative and nonoperative treatments, and 16 dealt with operative treatment of patients. According to the results of clinical outcomes in patients with consecutive thoracolumbar fractures and without any neurological complications, no difference is seen between the group undergoing operative treatment and the other one undergoing nonoperative treatment. As most studies were conducted on patients without any neurological complications, it was impossible to compare operative and nonoperative treatments in patients suffering from neurological complications. According to the results achieved in this research, operative treatment was much better than its nonoperative counterpart. This difference can be attributed to the method of execution. Bakhsheshian et al\textsuperscript{[14]} conducted a review research and studied each method separately, but the present research was a clinical trial where 2 methods were compared with one another. Gnanenthiran et al\textsuperscript{[16]} carried out a meta-analysis to compare operative and nonoperative methods to treat consecutive thoracolumbar fractures. The following 5 characters were used as keywords to search for papers in PubMed and EMBASE:

### Table 7
Comparison of average length of returning to work in terms of months for patients suffering from thoracolumbar in both groups.

| Length of returning to work/group | Nonoperative group | Operative group | $P$-value |
|----------------------------------|-------------------|----------------|-----------|
| Average length of returning to work | $1.05 \pm 0.85$ | $3.2 \pm 1.1$ | $P \geq .01$ | Significant |

### Table 8
Comparison of average age in terms of days for patients suffering from thoracolumbar in both groups.

| Age/group | Nonoperative group | Operative group | $P$-value |
|-----------|--------------------|----------------|-----------|
| Average age | $49.5 \pm 6.5$ | $48.5 \pm 6.7$ | $P \geq .05$ | Not significant |

Figure 4. Comparison of RSA angle score in patients suffering from thoracolumbar fracture before and 3, 6, 9, and 12 months following operation in both groups. RSA = regional sagittal angles.

In the end, some 4 studies including 2 clinical trials were selected for further analysis. According to these studies, 79 patients in 2 groups (41 in operative treatment group and 38 in nonoperative treatment group) were examined. According to the results, there is no significant difference in terms of the frequency of patients who returned to work after trauma and treatment ($P = .76$). The rate of return to work was 70% for those undergoing operation, while this rate was 67% for nonoperative treatment group. Although the frequency of Kyphosis deformity in operative treatment group was significantly less than what was observed in nonoperative treatment group, the complications and costs in operative treatment group was significantly more than nonoperative group. Kyphosis degree also exhibited no statistically significant difference between the 2 groups. No statistically significant difference was observed between the 2 groups in terms of pain ($P = .71$). Less pain, earlier return to work, and less RSA angle were the advantages of operative method observed in this research. Different sample sizes may explain the difference between these 2 researches. The guideline used in nonoperative group was also different from the present research as physiotherapy is used in nonoperative method while there was no physiotherapy in the current research.

Siebenga et al\textsuperscript{[15]} conducted a research on treating trauma-caused thoracolumbar fracture by comparing operative and nonoperative treatments with one another.\textsuperscript{[15]} As many as 34 patients were randomly divided into operative (18 patients) and nonoperative (16 patients) groups with due observation of inclusion and exclusion criteria. The patients were studied for 4 years and their demographic factors, fracture categories, radiological assessments, and outcome of performance were studied. Of 34 patients, 32 completed the research. According to the final results, Kyphotic deformity in operative groups was significantly more than nonoperative group, although outcome parameters of patients such as returning to the previous job was significantly more in operative group. Higher pain scores were reported in operative group than its nonoperative counterpart. They declared that patients with thoracolumbar fractures who have no neurological complication can use nonoperative treatment.\textsuperscript{[15]} However, the results achieved in our research found less pain, shorter period of return to work, and smaller RSA angle in operative treatment group. This difference is probably attributed to the relatively longer follow-up period in Siebenga et al’s research\textsuperscript{[15]} and the greater sample size in each group in our research. Denis et al\textsuperscript{[15]} conducted a research in order to compare operative and nonoperative treatments in patients with consecutive thoracolumbar fractures without neurological complications. 52 patients took part in this research. According to the results, all patients in operative group returned to their job after treatment, while 25% of nonoperative treatment did not. According to their results, 17% of the patients in nonoperative group got afflicted with neurological problems which were significantly more than operative group. Operative
method yields better results. The results of that research are in line with the results achieved here.

In conclusion, lower levels of pain score were reported in operative treatment group. A significant difference was observed among the patients with thoracolumbar fracture in both therapeutic groups in terms of RSA angle in all times studied. The RSA angle among patients undergoing operative treatment was smaller. The average length of returning to work in operative treatment group was shorter than what was observed in nonoperative group. Less pain, shorter length of returning to work, and a smaller RSA angle were observed in operative therapeutic group. This method is recommended for patients without any neurological defects.

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