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Functional Outcome of Surgical versus Conservative Therapy in Patients with Traumatic Thoracolumbar Fractures and Thoracolumbar Injury Classification and Severity Score of 4; A Non-randomized Clinical Trial

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ABSTRACT

Objective: To compare the effectiveness of surgical intervention to conservative treatment in patients with thoracolumbar fracture and thoracolumbar injury classification and severity score (TLICS) of 4.
Methods: Twenty-five patients with TLICS 4 were enrolled in this non-randomized clinical trial. Based on clinical symptoms and radiologic findings, patients were considered under surgical or conservative treatments. The JOA Back Pain Evaluation Questionnaire (JOABPEQ) was assessed at baseline and at 3, 6, 12 months after treatment. A 20-point improvement from the baseline JOABPEQ scores was considered as clinical success in both the conservative and surgery groups. Additionally, residual canal, angulations and height loss were determined in all patients.
Results: Eight patients received conservative and 17 surgical treatment. Both study groups were comparable regarding the baseline characteristics. Both study demonstrated treatment success, regarding functional recovery when compared to baseline (p<0.001). However, those undergoing surgical intervention had significantly better JOABPEQ score (p<0.001) and higher residual canal (p=0.042) when compared to those receiving conservative therapy. The success rate of treatment was comparable between the two study groups in 6- (p=0.998) and 12-month (p=0.852) intervals; however, surgical therapy had significantly higher success arte in 3-month interval (p=0.031).
Conclusion: Our findings revealed that surgical treatment was preferred more in comparison to conservative treatment in patients with TLICS 4. Additionally, residual canal might be a modifying factor to decide the ideal therapeutic approach.
Clinical Trial Registry: IRCT2017010920258N25

Keywords: Thoracolumbar fracture; Classification score; JOABPEQ; Residual canal; Thoracolumbar Injury Classification and Severity (TLICS).

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Introduction

Thoracolumbar and lumbar spine is the most susceptible site of major spinal injury, which can result to spinal cord damage and consequent irreversible neural deficits. They account for approximately 15% of all spinal injuries which seems to be due to lordotic posture, more sagittally oriented facet joints and lack of stabilized articulation with the ribs [1, 2]. The most important challenge in approach to thoracolumbar fracture is acknowledgement of the severity of damage and more important, the prognosis [3]. Various classification systems have been proposed for the evaluation of the thoracolumbar fracture. Currently, the thoracolumbar injury classification and severity score (TLICS) has been used for decision-making in patients with thoracolumbar injury. Based on this classification system, the patients with a score equal or more than five would be candidate for surgery, whereas conservative treatment would be the choice for the patients with the score less than four. However the ideal method of treatment for the patients with TLICS 4 is still controversial [4-10].

In this group, both surgical and conservative methods could be adopted. Each of these methods has its advantages, for example lower cost and less complication in non-operative method and faster recovery in operative treatment, respectively. So the accurate determination of which patients do not require surgery is highly beneficial [5, 11the authors formulated a treatment algorithm. METHODS: The authors reviewed the current literature on MIS treatment of thoracolumbar trauma. Based on the literature review, they then created an algorithm for the treatment of thoracolumbar trauma utilizing MIS techniques. This MIS trauma treatment algorithm incorporates concepts form the Thoracolumbar Injury Classification System (TLICS]. In addition, the JOA Back Pain Evaluation Questionnaire (JOABPEQ) is a well-known tool for measuring functionality in five domains including low back pain, lumbar function, walking ability, social life function and mental health in patients with low back pain [12]. It should be noted that, new studies are under way to establish other factors which might influence the decision making. Recently, it was suggested that age and residual canal were the predictive factors of success or failure in non-operative treatment of thoracolumbar injury [13]. Although several studies have been conducted, but the results are conflicting and there is no consensus accordingly [14-17].

According to the challenge of best therapeutic approach and more important, the statistical difference in recent reports, this study aimed to compare the effectiveness of treatment in patients with thoracolumbar injury and TLICS of 4 who were under operative or non-operative treatment methods based on the JOABPEQ questionnaire. In addition, other radiologic factors in were assessed in both groups to define a decision matrix for surgery or conservative treatment in patients with thoracolumbar injury and TLICS of 4.

Material and Methods

Study Population

This was non-randomized clinical trial which was conducted in Imam Hossein hospital, tertiary healthcare and trauma center affiliated with Shahid Beheshti University of Medical Sciences, Tehran, Iran from 2017 to 2018. Totally, 265 patients of any sex and age who were newly diagnosed with thoracolumbar fracture were enrolled. The diagnosis of thoracolumbar fracture was made based on clinical symptoms, neurological examinations, and imaging studies, including plain radiography, computed tomography (CT), and magnetic resonance imaging (MRI) of the thoracolumbar spine. Consequently, the TLICS score was evaluated and the patients with TLICS 4 were elected (25 patients). Patients were excluded in patients with osteoporotic fractures or with histories of previous spine surgery, systemic disorder or chronic pain. The study was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran (Code: IR.SBMU.MSP.REC.1397.785). The study protocol is also registered with Iranian registry of clinical trials (IRCT2017010920258N25). Also, we declare that written informed consents were obtained from all patients prior to their inclusion in this study.

Study Protocol

The choice of treatment method was determined according to patient's clinical status as age, the degree of injury or damage type, simultaneous injury, neurologic deficit, degree of residual canal, height loss, vertebral angulation and patients' satisfaction. In those undergoing surgery, pedicular screw fixation with posterolateral fusion and laminectomy was performed with aim of decompression and restoration of spinal column alignment. Long segment fusion and short segment fusion was considered in T12-L2 and L3-L4 fracture, respectively. Conservative treatment included bed rest and bracing until the pain abated sufficiently to allow mobilization and compression for deep vein thrombosis prophylaxis.

Outcome Measures and Follow-Up

In the following cases, JOABPEQ questionnaire was used to assess the functionality in five domains including low back pain, lumbar function, walking ability, social life function and mental health at admission and at the interval of 3, 6, 12 months after treatment. The possible score on the JOABPEQ ranged from 0 to 100 with higher scores indicating better conditions. Clinically, if the post-treatment score increased by 20 points in comparison to the pretreatment score or the pretreatment score was <90 and the post-treatment score reached 90 points; the

treatment was considered successful [12].

Statistical Analysis

After data collection, for continues variables, we reported mean and their associated standard deviation (SD) and for dichotomous variables, the frequency tables and percent were provided. We used t-test to compare the mean of function scores at baseline, 3 months, 6 months and 12-month follow-up in each treatment group. Moreover, we used analysis of variance for repeated measure t-test to evaluate the total trend of functional score improvement over the 12 months and to compare the improvement trend between the two groups. All statistical analysis was carried out using Stata (version 11, College Station, Texas, USA).

Results

Overall we have screened 265 patients with thoracolumbar fractures of whom only 240 met the inclusion criteria and they were allocated to two study groups non-randomized. All the patients finished the study and thus the final number of included patients in the final analysis was 25 (Figure 1). As demonstrated in Table 1, patients in two study groups were comparable regarding the baseline characteristics. Only those in surgical group had significantly higher rate of canal involvement (p=0.036).

In conservative group, the mean score of low back reached 28.56 in 3 months followed by 42.85 in 6 months and 57.12 in 12 months after initiating conservative treatment. According to t-test, there was a statistical difference between the low back pain score in each time interval between surgical and conservative group. By using repeated measure test, the effect of time on low back pain among the patients who underwent either surgical or conservative treatment was statistically significant (p<0.001). Moreover, the trend of improvement in surgical group was significantly higher than the conservative group (p<0.001) (Figure 2).

Mean score of lumber function at the first measurement in surgery group was 0.0 and continuously increased to74.07 in 3 months, 90.73 in 6 months and 96.29 in one year after surgery. For conservative treatment group, the lumber function mean score was 9.52 at the beginning of study, which reached to 36.90 in 3 months, 51.18 in 6 months and eventually 58.33 in 12 months after starting treatment. We showed the difference in each time interval to be significant between the two groups (p<0.001). Repeated measure test depicted the observed increased score in both groups to be statistically significant (p<0.001), which was

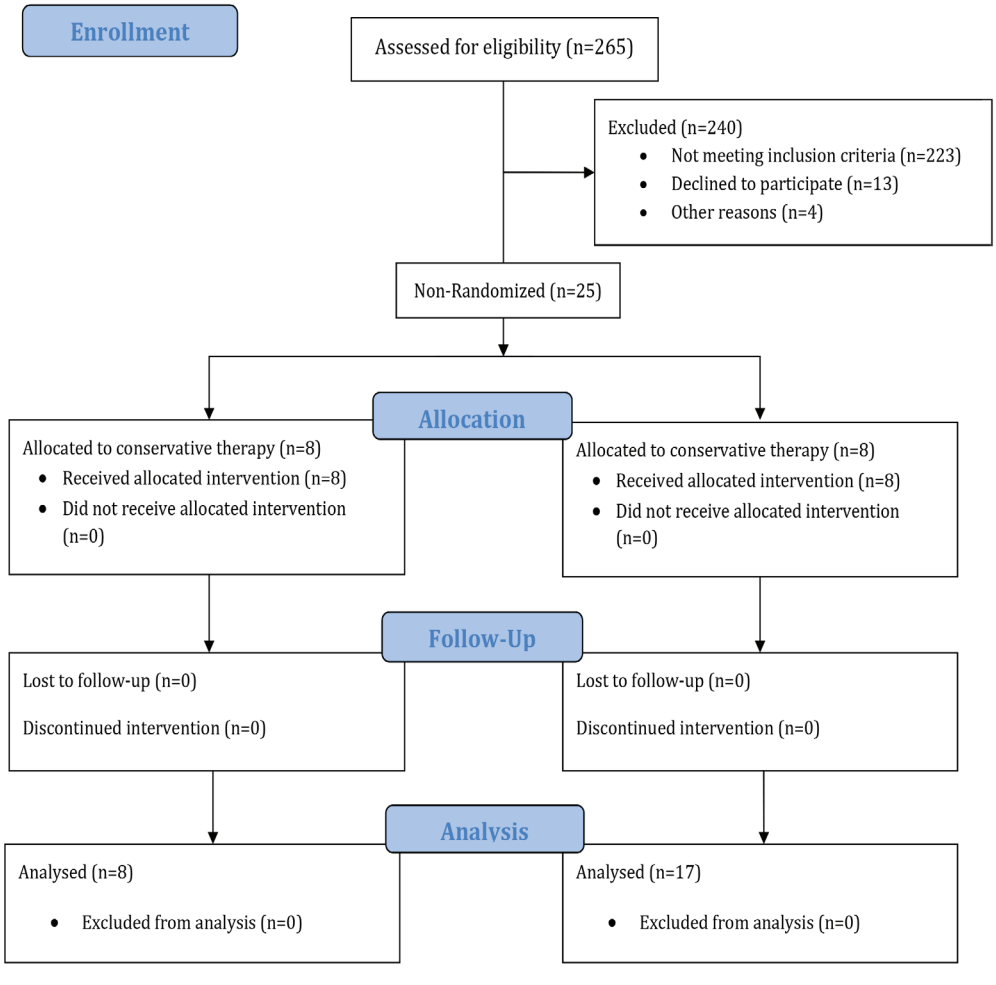

Fig. 1 CONSORT flow diagram of the study.

Table 1. The baseline and radiologic characteristics of 25 patients with thoracolumbar fractures in two study groups.

Variable	Surgical treatment (n=17)	Conservative treatment (n=8)	P value
Age (years)	42.815.1±	36.719.1±	0.078
Height loss (%)	29.10.1±	26.201±	0.332
Angulation (degree)	0.110.1±	0.1401±	0.291
Canal involvement (%)	27.50.1±	16.301±	0.036
Level			0.182
T10 (%)	3 (17.6%)	1 (12.5%)	
T11 (%)	4 (23.6%)	1 (12.5%)	
T12 (%)	5 (29.4%)	2 (25.0%)	
L1 (%)	3 (17.6%)	1 (12.5%)	
L2 (%)	1 (5.9%)	1 (12.5%)	
L3 (%)	1 (5.9%)	2 (25.0%)	
Co-injury			0.262
Limb fracture (%)	6 (35.3%)	3 (37.5%)	
Pelvic (%)	5 (29.4%)	2 (25.0%)	
Chest	3 (17.6%)	1 (12.5%)	
Head and Neck (%)	2 (11.8%)	1 (12.5%)	
Abdomen	1 (5.9%)	1 (12.5%)	

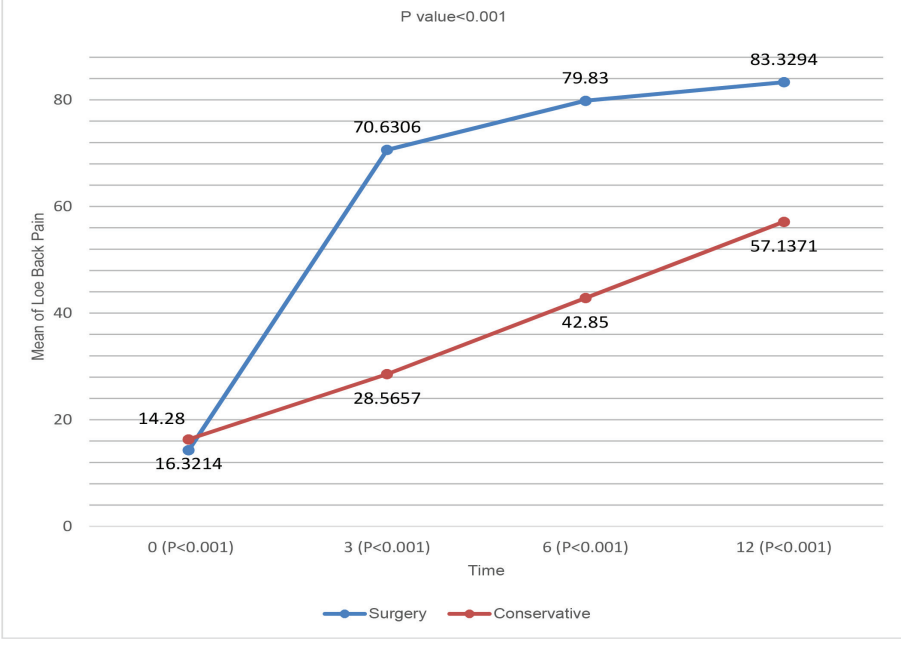

Fig. 2. Comparison of low-back pain score at the beginning of the study, 3 months, 6 months and 1 year follow-up between conservative and surgical group. There was a significant difference between two groups in each time period (p<0.001) and the total trend of functional improvement was significantly higher in surgical group (p<0.001).

significant in the surgical group in comparison to conservative group too (p<0.001) (Figure 3). We also assessed walking ability for consecutive times for both groups. In the beginning of study, it was 0.0 for both surgery and conservative groups. During the study period, it increased continuously in both groups and reached to 78.17 over 3 months, 86.50 over 6 months and eventually 93.65 at the end of our investigation in surgery group and 20.48, 41.83 and 60.20 over the mentioned time intervals in the conservative treatment group, respectively. Similar to previous variables, there was a dramatic difference between the mean score of walking ability in each time (p<0.001). Additionally, although the increase in both groups was significant (p<0.001), there was a statistical difference between the trend of improvement over the time between the two groups too (p<0.001) (Figure 4).

Moreover, we assessed social life function score for both groups. At arrival, mean score of social life function was 9.11 in the surgery group, which continuously increased to77.86, 89.05 and 90.19 over the mentioned periods, respectively. On the other hand, in the conservative group, the mean score of social life was 16.09 which reached to 39.91, 63.24 and 73.47, respectively. The results of the t-test and repeated measure test revealed a statistical difference between the mean score of the two groups over the defined intervals (p<0.001) and the increase in both groups was statistically significant (p<0.001) and with a significant difference in functionality improvement trend between the two groups

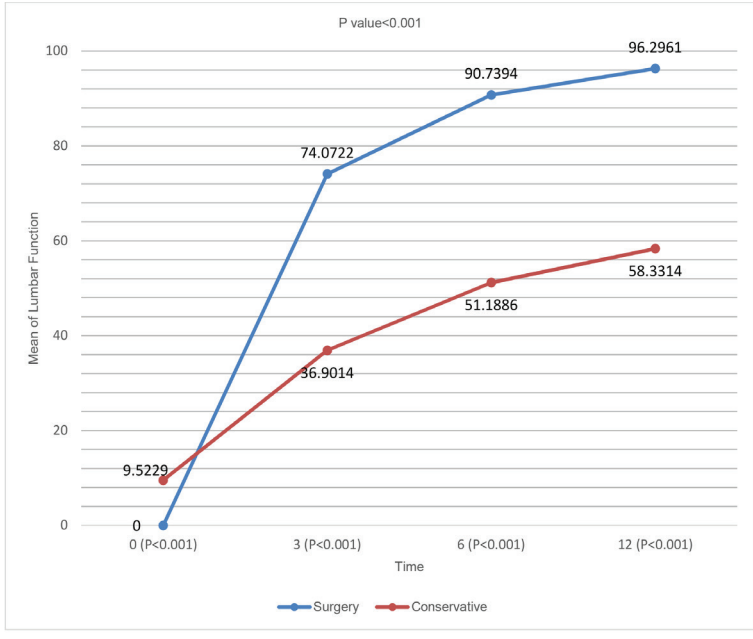

Fig. 3. Comparison of lumbar function at the start of study, 3 months, 6 months and 1 year follow-up between conservative and surgical group. There was a significant difference between two groups in each time period (p<0.001) and the total trend of functional improvement was significantly higher in surgical group (p<0.001).

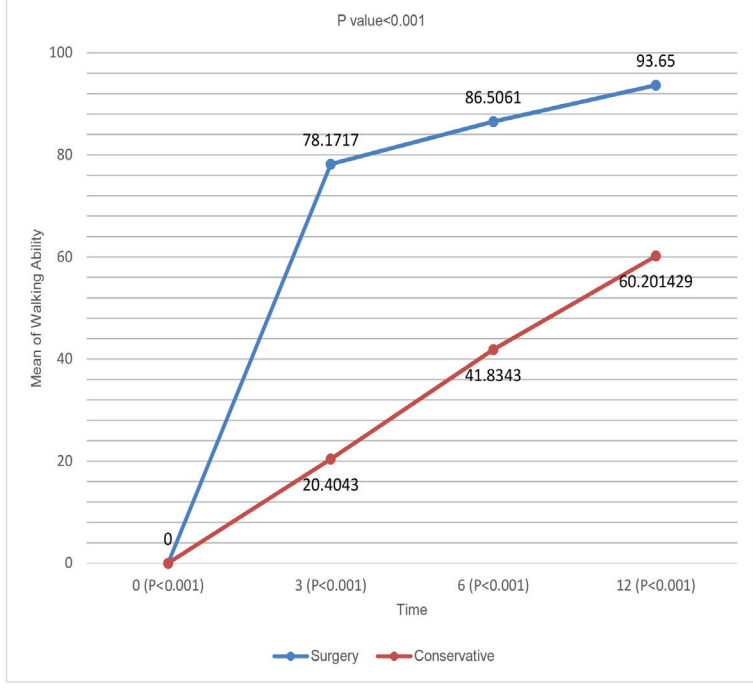

Fig. 4. Comparison of walking ability at the start of study, 3 months, 6 months and 1 year follow-up between conservative and surgical group. There was a significant difference between two groups in each time period (p<0.001) and the total trend of functional improvement was significantly higher in surgical group (p<0.001).

(p<0.001) (Figure 5). Furthermore, we evaluated the mean score of mental health. In the surgery group, it was primarily estimated to be 20.49 which reached to70.22, 84.70 and eventually 94.92 in various time intervals, respectively. In the conservative group, the primary score was 20.10, which continuously increased to 45.49, 71.98 and 78.26, in various time intervals, respectively. The difference between the mean score of the two groups in each time interval was statistically significant (p<0.001). All the investigated measures increased during a year in both groups which was significant too (p<0.001). However, despite other variables, there was not any statistical difference of functionally improvement trend between the two groups (p=0.06) (Figure 6). The summary of our results regarding comparison of low-back pain, lumber function, walking ability, social life function at the start of study, 3 months, 6 months and 1 year follow-up by treatment groups was presented in Table 2. Eventually, we assessed the effectiveness of the treatment between both groups shown in Table 3. Our findings demonstrated

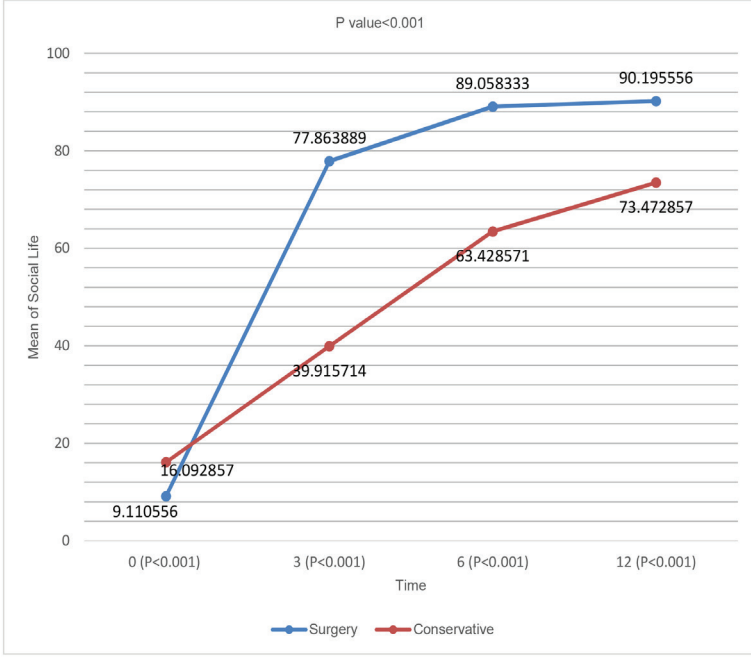

Fig. 5. Comparison of social life function score at the start of study, 3 months, 6 months and 1 year follow-up between conservative and surgical group. There was a significant difference between two groups in each time period (p<0.001) and the total trend of functional improvement was significantly higher in surgical group (p<0.001).

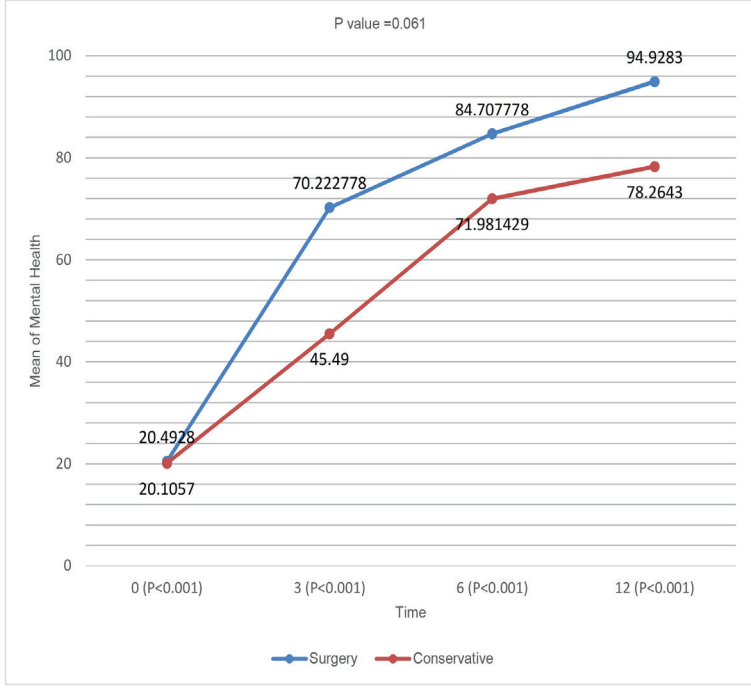

Fig. 6. Comparison of mental health score at the start of study, 3 months, 6 months and 1 year follow-up between conservative and surgical group. There was a significant difference between two groups in each time period (p<0.001) and there was not any statistical difference in the context of total trend of functional improvement between the groups (p=0.06).

although both surgical and treatment methods were ultimately successful, the primary success over first three months was visible only in the surgical group (Table 3).

Discussion

The TLICS score is the acceptable current classification system which is used to assist in the analysis and management of patients with thoracolumbar fracture [4]. This score contributes the appropriate decision regarding the necessity of surgical or nonsurgical management. However, the preferred method of treatment in patients with TLICS 4 is still controversial [4-10]. Inadequate research has been done on the patients' functionality status with thoracolumbar injury and TLICS 4. In additional the results are controversial.

In this study, we evaluated the patients with TLICS 4 who were under surgical or conservative treatment.

Table 2. Comparison of low-back pain, lumber function, walking ability, social life function at baseline, 3 months, 6 months and 1-year follow-up in each group.

	Surgical group (n=17)	Conservative group (n=8)	P value
Low-back pain			
Baseline	14.280.00±	16.325.40±	0.072
3 months	70.6326.14±	28.5624.74±	<0.001
6 months	79.8322.62±	42.8535.95±	<0.001
12 months	83.3217.83±	57.1330.86±	<0.001
Lumbar function			
Baseline	0.000.00±	9.52225.19±	0.058
3 months	74.0728.99±	36.9026.72±	<0.001
6 months	90.7320.78±	51.1830.58±	<0.001
12 months	96.2912.20±	58.3331.54±	<0.001
Walking ability			
Baseline	0.000.00±	0.000.000±	*0.999*
3 months	78.1727.22±	20.4018.63±	<0.001
6 months	86.5020.77±	41.8332.05±	<0.001
12 months	93.6516.59±	60.2038.21±	<0.001
Social life			
Baseline	9.1112.79±	16.0912.98±	*0.125*
3 months	77.8617.77±	39.9119.52±	<0.002
6 months	89.058.97±	63.4225.41±	<0.035
12 months	90.1910.19±	73.4725.46±	<0.089
Mental health			
Baseline	20.4917.58±	20.109.33±	0.887
3 months	70.2231.26±	45.4925.16±	<0.003
6 months	84.7018.24±	71.9827.80±	0.214
12 months	94.9212.13±	78.2622.31±	0.062

Table 3. Percentage of treatment effectiveness in surgery and conservative treatment groups at the start of study, 3 months, 6 months and 1 year after treatment.

Period	Surgical group (n=17)	Conservative group (n=8)	P value
3 months	17 (100%)	5 (62.5%)	0.031
6 months	17 (100%)	8 (100%)	0.998
12 months	16 (94.1%)	8 (100%)	0.852

It was found that although both non-operative and operative groups successfully completed their treatment over a year, the early effectiveness of treatment was only achieved in surgical group. Furthermore, we used the JOABPEQ questionnaire, which had never been used in previous studies and provided the opportunity to evaluate the functionality in five categorized domains including low back pain, lumbar function, walking ability, social life function and mental health.

According to this questionnaire, we revealed a significant difference of the functionality improvement rate trend between surgical and conservative groups in all domains over the mentioned time intervals (p<0.001), except for the mental health domain (p=0.061); despite the functional improvement in all domains over the time of both group. This non-statistical significant difference might be due to the small sample size. As the sample size increased in subsequent studies, this difference was statistically significant.

In addition, our results revealed a significant difference between the mean score of all the functional domains in each time interval between the surgical and conservative groups (p<0.001). In the surgical group, the most significant improvement was observed in lumbar function and walking ability domains. In a way that the primary score increased from 0 to 96.29 in lumbar function domain and from 0 to 93.65 in walking ability domain at the end of the study, respectively. Conversely in the conservative group, this increase was seen with a milder slope in the walking ability domain which revealed an increase from 0 to 60.20.

Taking into account all the clinical considerations, we assumes the quality of life to be influenced by even the slightest pain and functional limitations and the statistical discrepancy obtained in our study between the two groups to be in favor of surgical group versus conservative treatment and the acceptance of the initial costs of the surgery and hospitalization period for a better quality of life. The two current studies in the literature focused on the outcome of the patients with thoracolumbar fracture and TLICS 4 which are challenging.

In the study of Nararaj *et al*., they retrospectively observed 230 patients with thoracolumbar fracture who were hospitalized in their center from 2007 to

2013. The patients with TLICS 4 (47 patients) were enrolled in the study to evaluate the effectiveness of surgical or non-surgical treatment based on ODI and mean time to work. Their findings revealed no statistical difference between surgical and non-surgical group after 6 months (12). Conversely, in the double blind-clinical trial study of Mohammadi *et al.* on 50 patients (25 patients under surgical treatment and 25 patients under conservative treatment) with thoracolumbar injury and TLICS 4, the one year prognosis was better in patients who were under surgery which confirmed our results. [17]. The study of West *et al.* introduced sternum fracture, rigid spine, multiple rib fracture at the same level, wound and pre-existing deformity as the modifying factors in decision making process of the patients with thoracolumbar fracture [14]. Also, in the study of Azhari *et al.* on the patients with non-operative treatment with TLICS less than four, the residual canal was considered as a factor which was more involved in patients who were under surgery [15]. In recent years, it has been focused on patients' prognosis following thoracolumbar fracture. The study of Nataraj *et al*. evaluated the long term outcome of patients with thoracolumbar fracture and TLICS of 4. Their findings revealed no statistical difference between surgical and non-surgical therapy [16]. In contrast, in the study of Mohamadi *et al*. on patients with thoracolumbar injury and TLICS 4, they found that one year prognosis was better in patients who had been under surgery [17].

However, in both studies, the sample size was greater than our study; which was more likely to provide a more rational inference. On the other hand, in the study of Nataraj *et al*., the evaluation of the patients was limited only to six months after the initial treatment, which might have missed the early post treatment status of the patients. This challenge has also been observed in the old studies, as the study of van der Roer *et al*. who did not reach a reliable response for effectiveness of whether operative or conservative treatment for unstable traumatic thoracolumbar fractures [18]. The study of Wood *et al.* also revealed no benefit for surgical over nonsurgical treatment of stable burst fractures [19].

Another aspect of our work was considering other radiologic factors, which might contribute to appropriate decision amking. We evaluated three radiologic variables including of residual canal, vertebral angulation and height loss. Our results indicated to a statistical difference between residual canal in operative and non-operative groups. However, no significant difference was observed between the two groups in terms of height loss and vertebral angulation. We assume this is an important matter that might introduce the residual canal as a modifying factor in decision making process in patients with TLICS 4.

However, the small sample size of our study constraint a proper interpretation. Additionally, we were not able to provide a cut-off value of the residual canal to identify the patients who might benefit the surgery. Our findings were in parallel to Azhari *et al*.'s study [15], who recommended the age and residual canal as the modifying factors in decision making process. It is worth noting that the most strength key point of our study compared to Azhari *et al*.'s study was the patient collection. In this study, we enrolled the patients with thoracolumbar fracture and TLICS 4 in which there was still universally a challenge of best therapeutic approach.

As mentioned, little research has been done on the patients with thoracolumbar injury and TLICS 4 and less has been done on the functionality status of these patients. In the last decade, there has been more interest to determine other modifying factors involved in the assessment of best medical approaches in patients with thoracolumbar injury as the work of West *et al.* who introduced sternum fracture, rigid spine, multiple rib fracture at the same level, wound and pre-existing deformity as the modifying factors in decision making process of the patients with thoracolumbar fracture [14, 20-22].

It should be noted that there is a lack of convincing evidence in the literature to provide a quite distinct guideline in approaching patients with thoracolumbar fracture and TLICS 4. Regarding the importance of functional status in patients with thoracolumbar injury, we particularly focused on the functional outcome of the patients with thoracolumbar injury and TLICS 4 who were under either operative or non-operative treatment. In this study we revealed the superiority of surgery to conservative treatment in the first three months. Furthermore, despite the eventual success of both therapeutic strategies, we showed a significant difference between surgical and conservative groups for all functional domains over the whole periods based on the JOABPEQ questionnaire (p<0.001). More ever, the trend of functionality improvement was significantly higher in the surgical group in all domains except for the mental health in comparison to conservative treatment (p<0.001). However, due the lack of statistical difference of the functional status at arrival between the two groups, we could not provide a cut off value for the functional status.

In addition, we suggest the residual canal might be considered as a modifying factor in decision making process in patients with TLICS 4, which need more comprehensive researches with a sufficient sample size to be confirmed. Currently, the TLICS score is the acceptable classification system in patients with thoracolumbar injury. However, it has its own limitation in which absence of considering functionality status as a factor to assess the effectiveness of treatment is in paramount of importance.

In conclusion, the results of the current study indicates that in patients with thoracolumbar injury, although complete success was seen in both operative

and non-operative groups, the surgery was preferred more in comparison to conservative treatment, due to better improvement of functionality score based on the JOABPEQ questionnaire. In addition, we came to the conclusion that canal involvement was more evident in surgery group in comparison to conservative group. As a result, we suggest the residual canal to be considered as a modifying factor in appropriate therapeutic approach. However, due to small sample size, we highly recommend more researches to confirm our findings.

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Conflict of Interest: None declared.

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