



Research Paper: The Role of Post-Traumatic Stress Disorder and Self-Efficacy Beliefs on the Quality of Life of Patients With Traumatic Spinal Cord Injury



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Bullet Points:

- The QOL of SCI patients improves with the decreases in symptoms of PTSD and increasing self-efficacy beliefs.
- The prevention and treatment of PTSD and promoting self-efficacy beliefs in SCI patients can improve their QOL.
- The signs of PTSD and self-efficacy beliefs explained 66% of the total variance of SCIQL-23 scores.

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ABSTRACT

Background: Spinal Cord Injury (SCI) and its post-traumatic stress remarkably influence the patients' Quality of Life (QOL). Besides, some health determinants such as self-efficacy beliefs can change QOL of patients, too.

Objectives: To determine the role of Post-Traumatic Stress Disorder (PTSD) and self-efficacy beliefs on the QOL after traumatic SCI.

Materials & Methods: Out of 133 SCI patients studied from Spinal Cord Injury Center of Rasht City (North of Iran), 90 qualified for this cross-sectional study. A senior psychologist conducted structured interviews for 70 people at the center and another 20 patients at their homes, because of their inability to come to the center. Data collection instruments were researcher-made questionnaire containing both individual-social and lesion-related variables, post-traumatic stress scale for DSM-5, Sherer general self-efficacy questionnaire and the SCIQL-23 (Spinal Cord Injury Quality-of-Life-23) questionnaire (to assess the QOL in patients with SCI). The obtained data were analyzed by SPSS through the Pearson correlation coefficient, Independent student t test and hierarchical regression analysis (after adjusting confounding demographic factors).

Results: Correlation coefficients showed that the QOL of SCI patients decreases ($P < 0.0001$) with an increase in symptoms of PTSD and improves ($P < 0.0001$) with increasing self-efficacy beliefs. Hierarchical regression analysis also revealed that after removing the effect of the confounding variables (duration of lesion, gender, type of lesion, having a bed sore, catheter, nurse, diaper, wheelchair), signs of PTSD ($F = 7.38$, $P < 0.0001$) and self-efficacy beliefs ($F = 18.35$, $P < 0.0001$) significantly explained 66% of the total variance of SCIQL-23 scores.

Conclusion: The results of this research stresses on the prevention and treatment of PTSD and promoting self-efficacy beliefs in SCI patients in order to improve their QOL.

Keywords: Quality of Life, Spinal cord injuries, Self-efficacy, Stress disorders, Post-traumatic

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Introduction

Spinal Cord Injury (SCI) is a disabling disorder that brings a lot of physical, psychological and socio-economic burden for the patients. It is not surprising that right after this event, the appeared mental disorders last and affect different areas of the Quality of Life (QOL) of these people [1, 2]. With regard to over 270000 people with SCI in USA and 12000 new cases every year, the QOL of these patients is very important for therapists [3]. It is considered one of the important health (physical, social and mental) indicators [4].

A study conducted in Iran on mental health and the QOL of SCI patients concluded that QOL and the mental health status of these patients are weaker than the normal people [5]. One striking thing is that QOL in SCI patients improves shortly after the accident. In this regard, it seems that both cognitive components (which help life satisfaction) and the emotional component (which relates to the mental health of the affected person) outshine the QOL [6].

Post-Traumatic Stress Disorder (PTSD) is a common disorder (31.5%) after traumatic events in Iran [7, 8] which according to the fifth edition of the Diagnostic and Statistical Manual (DSM-5), is characterized with four criteria of re-experience, avoidance, irritability, and negative changes in the mood and cognition [9]. Because of avoidance and stigma, this disorder often remains without diagnosis and treatment [7, 10]. Otis et al. [11] in a sample of 111 SCI patients found that 11% met the PTSD diagnostic criteria and another 20% were to some extent qualified according to the diagnostic criteria for PTSD. In this study, risk factors associated with PTSD symptoms were trauma history, pre-traumatic reactions, and intolerance towards uncertainty.

Self-efficacy means the person's confidence in his abilities to do particular behaviors in different situations. Self-efficacy can improve self-care, adaptability, life satisfaction, and QOL [12]. Self-efficacy, as a belief in own abilities, plays an important role in reducing the symptoms of mental disorders [13]. Studies have shown that focus on enhancing self-efficacy can reduce the symptoms of depression and PTSD [14]. Besides, the researchers found that promoting self-efficacy believes, as one of the resources of personal empowerment, helps improve the QOL of the SCI patients [15].

Factors such as more mobility, better perceived physical health, social support, psychological performance

and self-efficacy are involved in the QOL of patients with SCI [6]. In this regard, Van Leeuwen et al. [16] in their systematic review found that higher QOL is always accompanied by higher levels of mental abilities such as the sense of total loss of control, sense of coherence, hope, having a purpose in life, and positive thinking. Moreover, both negative feelings and post-traumatic stress always exist with lower QOL. However, studies conducted on the QOL of patients with SCI and its related factors are few, and most of the studies have been conducted in countries such as the UK and the United States that are culturally different from Iran [6]. Therefore, the present study intends to answer the questions as what roles the PTSD signs, symptoms and self-efficacy believes have on the QOL of SCI patients.

Materials and Methods

Study participants

In this descriptive, cross-sectional study, 90 patients from the members of the Society of Spinal Cord Injuries in Guilan Province (N=133) passed the inclusion and exclusion criteria and gave consent for the psychological assessments and medical evaluations. Besides, to evaluate sample size adequacy in regression analysis, power analysis was used along with the help of a general linear model (described in the "Results" section). Finally, patients over 16 years of age who have passed six months of their SCI diagnosis entered the study, and those patients with congenital SCI were excluded from the sample group.

Study design and procedure

The research procedure is as follows: 38 patients from the SCI Association of Guilan and 32 patients from Guilan Welfare Organization were invited to their own sponsored organizations, and the rest of the patients who did not have the ability to visit these two sites (n=20) were interviewed at home. First, patients with SCI were visited by a physician and their physical problems were examined. Then a senior psychologist held structured interviews with them. Before conducting the research, the patients were assured of the confidentiality of their information that is going to be published as a general group response.

Study measures

Sociodemographic and injury characteristics

In order to conduct this study, a researcher-made questionnaire was designed to study the individual and so-

cial characteristics and related injuries (mechanism of damage, complications and consequences).

The Spinal Cord Injury Quality-of-Life-23 (SCI-QL-23) Questionnaire

The Spinal Cord Injury Quality-of-Life-23 (SCI-QL-23) questionnaire was designed to assess the QOL associated with the health of SCI patients [17]. This instrument has shown excellent reliability, and its Cronbach α coefficient has been reported to be more than 0.80 [18]. In Iran, the Persian translation of this instrument has been used as a sample for SCI patients with acceptable content validity [19]. The final question in SCIQL-23 is related to the General Quality of Life assessment (GQOL).

Other 22 questions are divided into three main subscales: 1. Function (FUNC): This variable evaluates the physical and social constraints in SCI patients; 2. Mood status (MOOD): It addresses the psychological state of the patients; 3. Problems related to the injury (PROB): This item tries to evaluate the level of independence and other issues related to the lesions in the SCI patients; and 4. General Quality of Life (GQOL): As the last question of this subscale, it shows the patient's life satisfaction. All scores in these areas, except for the GQOL section, ranges from 0 to 100. Getting higher scores in the three sections of FUNC, PROB and MOOD in this questionnaire reflect a weaker condition of QOL [17, 19].

Self-Efficacy Scale

The Sherer et al. self-efficacy scale was used to measure self-efficacy [20]. This scale has 23 questions, out of which 17 questions were dedicated to the general health and 9 other questions to the self-efficacy experiences under social situations. Sherer et al. [20] reported its Cronbach α as 0.86. Asgharnejad et al. [21] obtained the reliability of this scale as 0.88 using the Cronbach α coefficient. Najafi et al. [22] reported the reliability of this scale using Cronbach α as 0.80 and its construct validity as 0.91 using its correlation with the self-esteem scale.

DSM-5 PTSD's symptom

To measure PTSD symptoms in this study, Elhai et al. [9] instrument was used. They designed their instrument based on the Post-traumatic Stress Scale (PSS) which was previously made by Foa et al. [23]. Based on the DSM-5 criteria, Elhai et al. [9] designed a 20-item questionnaire (3 questions about clinical symptoms of

PTSD were added to the previous 17 questions). This instrument examines the most stressful accident in the last month and constitutes 20 items with a score of 0 to 3. The minimum and maximum scores are 1 and 60, respectively (0: Not at all; 1: Once in a week [rarely]; 2: Two to four times a week [sometimes]; and 3: Five times and more in a week [always]) in four clusters of symptoms. Re-experience of accident while awake or asleep (questions 1-5), avoidance meaning ignoring any symptom which simulates the incident for the person (questions 6-7), negative changes in mood and cognition characterized by symptoms of guilt (questions 8-14), irritability characterized by symptoms of anger and nervousness (questions 15-20).

The goodness-of-fit for DSM-5 symptoms was obtained as very good, based on the confirmatory factor analysis and none of the factors were correlated with depression [9]. In Iran, the reliability of this scale was calculated by the internal consistency and the computation of the Cronbach α coefficient ($\alpha=0.88$); therefore, the PSS-DSM-5 showed a favorable reliability and validity [7].

Statistical analysis

Data of this research were analyzed using SPSS version 16 and the significant level was set at $P<0.05$. The Pearson correlation coefficient was used to measure the relationship between the interval variables. To compare scores of the patients' QOL in terms of demographic variables, complications of injury and lifestyle, the Independent student t test was used. Finally, to determine the role of independent variables in predicting the scores of the patients' QOL, hierarchical regression analysis was used after controlling demographic confounding factors.

Results

According to Table 1, the studied patients were 71(78.9%) men, 51(56.7%) married, 29(32.2%) with diploma education and 64(71.1%) unemployed. With regard to the cause of the injury, the most common cause was the fall with 24(26.7%) cases. The last question of SCIQL-23 revealed that 18.5% of patients were dissatisfied with their QOL, and only about 5% of them were generally satisfied with their QOL. Finally, the symptoms examination of PTSD showed the moderate effect of stress after the accident in 33(36.7%) patients and severe effect in 26(28.9%) patients (Table 1).

While examining the types of lesion, the highest percentage belonged to paraplegia lesions with 79(87.8%) cases. Also, diabetes was diagnosed in 3(3.3%) patients,

blood pressure in 5(5.6%) patients and increased blood lipids in 2(2.2%) patients. Bedsore was observed in 34(37.8%) patients, and 72(80%) patients had a nurse (caregiver). A total of 59(65.6%) patients used a wheelchair. Also, 49(54.4%) patients had the urine catheter, and 32(35.6%) used diapers. Seven (7.8%) people gave birth to a child after the lesion, and 79(87.8%) patients were covered by health insurance.

In this study, it was necessary that all the demographic confounding factors and disease characteristics that have a significant relationship with the criterion variable be controlled in the hierarchical regression analysis to ascertain the determinant role of PTSD symptoms and self-efficacy beliefs on patients' QOL. Therefore, the Independent student t test was used for categorical variables (Table 2) and Pearson correlation coefficient for interval variables (Table 3) to investigate socio-demographic

factors related to QOL. Of course, in these statistical analysis calculations, the patients with indistinctive responses to the demographic questions were excluded from the study.

According to the results in Table 2, a significant statistical difference was found between the compared groups with respect to the variables of lesion: duration, gender, paralysis situation, having a nurse, using wheelchair, catheter and diaper ($P \leq 0.05$). In other words; female patients; tetraplegic patients; those who have bedsores; nurse (caregiver); using wheelchairs, catheter and diapers; experience poorer QOL. Therefore, the above variables, which had a significant relationship with the SCIQL-23 overall score in the univariate analysis, were considered as confounding variables and their weight was controlled in hierarchical regression analysis.

Table 1. Demographic characteristics, global QOL and PTSD status of the SCI sample participants (N=90)

Characteristics	Categories	n (%)
Sex	Male	71(78.9)
	Female	19(21.1)
Marital statuses	Married	51(56.7)
	Single	33(36.7)
	Widowed	1(1.1)
	Unspecified	5 (5.5)
Education	Illiterate	3(3.3)
	Primary	20(22.2)
	High school	23(25.6)
	Undergraduate	29(32.2)
	Diploma	5(5.6)
	Bachelor	7(7.8)
	Higher	3(3.3)
Work status	Housewife	9(10)
	Unemployed	64(71.1)
	Employee	4(4.4)
	Farmer	1(1.1)
	Self-employed	11(12.2)
	Retired	1(1.1)

Characteristics	Categories	n (%)
Cause of injury	Pedestrian	12(13.3)
	Driver	12(13.3)
	Passenger	23(25.6)
	Motorcycle	11(12.2)
	Sportive	1(1.1)
	Falling	24(26.7)
	Other events	14(14.4)
Global Quality of life	Very dissatisfied	11(12.2)
	Dissatisfied	36(42.2)
	Satisfied	38(40)
	Very satisfied	5(5.6)
PTSD	None	1(1.1)
	Rarely	23(25.6)
	Medium	34(37.7)
	Much	26(28.9)
	Very much	6(6.7)

According to the results presented in Table 3, the mean (SD) age of patients was 39.03(11.09) year. The mean (SD) time elapsed from a traumatic spinal cord injury was 126.39(104.01) month and the mean (SD) hospitalization time was 47.82(50.55) day. With regard to the demographic variables, calculation of correlation coefficients between the studied variables revealed that the QOL of the patients, only has a relationship with the time elapsed lesion ($P<0.05$), i.e. lesser the time passed from the lesion, more will be the score of QOL of the patient (they will have a weaker quality of life). Therefore, the duration of the lesion was controlled as a confounding variable in the regression analysis. There was no statistically significant relationship between the total score of QOL and the variables of age, age at the time of lesion, and duration of hospitalization ($P>0.05$). But there was an inversely significant correlation ($P<0.05$) between the current age of the patient with the patient's age at the time of lesion ($r=-0.67$), and the duration of the lesion ($r=-0.32$). A reverse correlation was observed between the patient's age at the time of the lesion with the duration of the lesion ($r=-0.34$) and significant relationship between total PTSD score with the QOL ($P<0.0001$).

This means that by increasing the symptoms of PTSD, QOL scores also increases, i.e. the quality of life weakens (as in this instrument, earning higher scores means a drop in QOL). Finally, a strong and reverse relationship was observed between QOL and self-efficacy scores ($P<0.0001$), which reflects that with stronger belief in self-efficacy, QOL scores (in the path of improvement) reduces (Table 3).

Before the main statistical analysis, the assumption for normality of the criterion variable in the regression analysis of the total score of SCIQL-23 was investigated by histogram and matched with the normal curve. Thus, it became clear that standardized residuals of QOL score regression follow the normal distribution. Before performing this analysis, information of 8 patients was excluded from statistical calculations because of their missing data, i.e. more than 20% of their questionnaire information. Results from the Durbin-Watson test showed that the assumption of the independence of errors to perform regression analysis was not violated ($DW=1.963$). Though power analysis was used before implementing regression analysis in order to determine

Table 2. Spinal cord injury QOL-23 scores based on demographic variables and disease characteristics

Characteristics		n	Mean (SD)	t	P
Gender	Male	71	48.64(9.77)	2.56	0.01
	Female	19	55.06(9.40)		
Marital status	Married	51	48.34(10.39)	1.17	0.20
	Single	33	50.91(8.74)		
Lesion type	Tetraplegia	10	58.41(6.93)	2.91	0.005
	Paraplegia	79	48.98(9.91)		
Bedsore	Yes	34	55.32(8.82)	4.31	0.001
	No	56	46.76(9.32)		
Nurse use	Yes	72	51.23(9.61)	2.41	0.02
	No	18	45.05(10.25)		
Wheelchair	Yes	59	52.03(9.29)	2.76	0.007
	No	31	46.12(10.29)		
Urinary catheter use	Yes	49	52.42(9.61)	2.59	0.01
	No	41	47.10(9.78)		
Diapers	Yes	32	53.13(11.01)	2.26	0.02
	No	58	48.27(9.03)		
Having child	Yes	7	46.43(5.84)	0.93	0.30
	No	83	50.30(10.24)		
Having insurance	Yes	79	49.52(9.96)	1.21	0.20
	No	11	49.52(10.00)		

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the adequacy of the research sample size ($n=90$). The results of the general linear model showed that the test power for all the main variables (i.e. self-efficacy beliefs and signs of PTSD) was higher than 0.80 which indicated the sufficient sample size for regression analysis. Next, Table 4 presents the summary results of the regression model before and after controlling confounding variables in the form of models 1 and 2.

The results of Table 4 indicate that the R^2 and adjusted R^2 coefficients of the model improved after controlling the confounding variables in such a way that in the second or adapted model, about 66% of the changes in the QOL score can be explained by symptoms of PTSD ($F=7.38$, $P<0.0001$) and self-efficacy beliefs ($F=18.35$, $P<0.0001$).

Based on Table 5, the results of hierarchical regression showed that after removing the effects of confounding variables from the main variables; PTSD symptoms and self-efficacy beliefs, the total PTSD score significantly predicted the overall score of the quality of life. Signs of beta coefficients can be interpreted as the matrix of correlation coefficients obtained in this study. However, it can be said that both independent variables are effective ap-

proximately with the same power in predicting the QOL of SCI patients. This means that by one unit increase in the standard deviation, PTSD symptom scores will increase the QOL of patients by 0.34 (i.e. weakens QOL) and also by one unit increase in standard deviation of self-efficacy beliefs scores, the quality of life of patients drops by -0.35 of the standard deviation (i.e. improved QOL).

Discussion

This study showed that even after controlling demographic and injury-related factors such as the duration of the lesion; gender; type of lesion; having bedsore, catheter, nurse (caregiver), diaper, and wheelchair; symptoms of PTSD and levels of self-efficacy can predict changes in the QOL after the occurrence of SCI.

The findings of this study indicated a significant and direct correlation between PTSD and QOL in the SCI patients. These finding are also consistent with the findings of Van Leeuwen et al. [16]. In a systematic review of the relationship between psychological factors and QOL in SCI patients, they [16] revealed that negative feelings and post-traumatic stress are always associated

Table 3. Correlation coefficients for some demographic variables, PTSD, self-efficacy beliefs and QOL in SCI patients

Variables	Mean	SD	1	2	3	4	5	6	7	8	9	10
T_score (total) for SCIQL-23	50.00	10.00	1									
QOL_FUNC	13.88	7.33	0.923*	1								
QOL_Mood	7.45	4.74	0.880*	0.698*	1							
QOL_PROB	12.02	4.35	0.855*	0.664*	0.699*	1						
Current age (in year)	39.03	11.09	0.105	0.126	0.060	0.075	1					
Lesion age (in year)	28.34	11.55	0.150	0.136	0.137	0.128	-0.677*	1				
Lesion duration (in month)	126.39	104.01	-0.202*	-0.168	-0.209**	-0.170	-0.329*	-0.343*	1			
Lent of hospital- ity (in days)	50.55	47.82	0.244	0.275	-0.025	0.311	0.085	-0.276	0.389	1		
PTSD total score	25.73	11.08	0.624*	0.513*	0.599*	0.584*	0.001	0.00	-0.97	0.423**	1	
Self-efficacy total score	54.80	12.72	-0.675*	-0.618*	-0.621*	-0.555*	-0.203	-0.244**	0.237*	-151	-0.483*	1

*P<0.01; **P<0.05

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with lower QOL. Furthermore, the results of this study are consistent with the findings of Khodadadi et al. [24]. Their study showed that acute stress of the first week has been an independent predictor for symptoms of PTSD two months later. In a study based on European societies, the researchers found that by worsening the PTSD symptoms, the mental QOL of the patients decreases [25]. The same result was found in the patient population with mild traumatic brain injury. In addition, the researchers found that high levels of PTSD are associated with increased functional disability, and the same results can, in turn, lead to lower QOL of the patients [26].

Some researchers believe that “being alone” and “living alone” are independent risk factors for PTSD, especially for the disabled patients [26]. We also believe that imaginary or real fear from “being left alone” in SCI patients, besides worsening the negative mood, can increase the sense of helplessness, restlessness, remembering a bitter event leading to SCI, isolation, repeating

traumatic memories while isolation from all are components of PTSD.

According to the results of these studies, PTSD is a serious and debilitating illness caused by severe stress which an individual encounters and it is one of the disorders that not only can affect one's QOL but also affects his family and society. Family problems, depression, leaving work or study and duration of hospitalization can also be the basis for the onset of this disorder [7, 24].

The findings of this study indicate a significant and inverse correlation between self-efficacy and QOL in SCI patients. In other words, these findings showed that by promoting self-efficacy beliefs, the score of QOL decreases (in the path towards improvement). Previously, this protective effect of self-efficacy has been well-documented in healthy people [27] and even in patients with brain injury [28]. The results of this study are in line with the findings of Van Leeuwen et al. [16]. They reported that some psychological abilities such as the feeling of

Table 4. Hierarchical regression model for the QOL before and after controlling confounding demographic variables

Model	R	R ²	Adjusted R ²	Std. Error of the Estimate	Durbin-Watson
1	0.652	0.425	0.367	7.98064	1.963
2	0.838	0.702	0.663	5.49850	

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Table 5. Regression analysis for the QOL of SCI patients from symptoms of PTSD and self-efficacy after controlling the confounding variables

Final (Corrected) Model	Unstandardized Coefficients		Standardized Coefficients	t	P	95% CI	
	B	Std. Error	Beta			Lower	Upper
(Constant)	60.826	5.903		10.305	0.000	49.075	72.578
Lesion duration	-0.010	0.006	-0.108	-1.642	0.105	-0.023	0.002
Gender	2.862	1.699	0.115	1.684	0.096	-0.521	6.244
Lesion type	-3.980	2.024	-0.134	-1.966	0.053	-8.009	0.050
Bedsore	5.247	1.338	0.256	3.922	0.000	2.583	7.910
Urinary catheter use	0.570	1.625	0.028	0.351	0.727	-2.665	3.806
Nurse use	0.791	1.826	0.031	0.433	0.666	-2.844	4.426
Diapers	0.381	1.609	0.018	0.237	0.813	-2.821	3.584
Wheelchair	2.147	1.659	0.102	1.294	0.199	-1.155	5.450
PTSD	0.310	0.066	0.344	4.664	0.000	0.178	0.442
Self-efficacy	-0.275	0.062	-0.351	-4.429	0.000	-0.399	-0.151

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total loss of control, self-worth, hope, having a purpose in life, and positive thinking (which can be considered as self-efficacy elements) are associated with improved quality of life in SCI patients.

Our study results were also consistent with the findings of Jerusalem and Mittag [29]. They showed that self-efficacy has positive correlation with optimism, self-respect, inner control and motivation for progress while it has a negative correlation with anxiety, depression and psychosis. They showed that those with higher self-efficacy adapt better to life changes and ultimately improve different dimensions of their QOL [25]. With regard to the disabling diseases such as brain injury, some researchers believe that self-efficacy will improve the QOL of patients by eliminating the harmful effects of emotion-oriented coping. On the other hand, it became clear that even months after the brain injury, self-efficacy can have positive effects on the level of social participation from the patients which is strongly associated with their QOL [28].

What are the inferred clinical and applied implications from the findings of this study? Having a definitive answer to this question is difficult using a cross-sectional design for this study. However, it is recommended that behavioral interventions can be designed to reduce PTSD in SCI patients in which patients effectively face

their fears and use relaxation and emotional acceptance techniques to reduce PTSD symptoms. SCI patients are encouraged to reach the level of academic or working performance they had before SCI. Although in some cases this goal is unattainable, we have seen that reducing functional disability can be effective in improving PTSD [26]. On the other hand, the findings of this study suggest that the initial assessment of self-efficacy beliefs of patients, in managing complications of SCI, can re-identify patients who are potentially at risk of adverse consequences (such as loss of QOL).

Findings of this study imply that promoting self-efficacy beliefs in SCI patients can lead to a better outcome (especially in terms of quality of life). According to Bandura [30], self-efficacy is not an attribute, rather a generative capability, in which mastery of skills along with strong belief in what can be achieved with these skills are important. We believe that designing interventions to enhance personal skills, positive self-talking and avoiding self-blame, ability to maintain energy, effective coping with frightening aversive arousals, anxiety and tension all can increase the expectation of success in SCI patients.

Current study enjoys the advantage of having an appropriate and uniform sample size, but it should be noted that findings of this study cannot be generalized to other

groups suffering from damage to nervous system such as brain traumas. Our performed analysis answers to the questions that arose from the data of a cross-sectional study; therefore, any inference from the existing documentation is not permissible.

Conclusion

In this study, it was determined that even after controlling demographic factors, symptoms of PTSD and lower levels of self-efficacy beliefs can be the source of degrading QOL after SCI.

Ethical Considerations

Compliance with ethical guidelines

All ethics 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.

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Conflict of interest

The authors declare no conflict of interest.

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