

Effect of Milwaukee Brace on Quality of Life in Adolescents with Idiopathic Scoliosis

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Abstract

Introduction: Scoliosis is defined as a lateral deviation of the normal vertical line of the spine measured on radiography, with the curve greater than 10 degrees. One of the braces commonly used for scoliosis is Milwaukee. The purpose of this study was to evaluate the effect of Milwaukee brace on quality of life (QoL) in adolescents with adolescent idiopathic scoliosis (AIS) using the QLPSD questionnaire. **Material and Method:** Eighty-four patients (10-20 years old) with AIS were recruited. Patients divided into two groups: intervention group (with Milwaukee brace) and control group (without any interventions). The "Quality of Life Profile for Spine Deformities" (QLPSD) questionnaire was used to assess the individuals' QoL. The highest score indicates the lowest QoL and the lowest score indicates the highest QoL. The independent t-test was used to evaluate the difference between two groups. **Result:** There were a significant increase between two groups in total QLPSD score ($P=0.015$). Regarding the QLPSD dimensions, mental function ($P=0.003$), sleep disorders ($P=0.001$), self-image ($P=0.016$), and flexibility of spine ($P=0.018$) were increased in Milwaukee brace group compared with no intervention group. Pain differences in two groups was not significant ($P=0.061$). **Conclusion:** Using the Milwaukee brace reduced individuals' QoL with AIS. Due to the effective role of QoL on the treatment process, the Milwaukee braces should be prescribed cautiously.

Key words: Idiopathic Scoliosis, Milwaukee Brace, Quality of Life, QLPSD Questionnaire

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Introduction

Scoliosis is defined as a lateral deviation of the normal vertical line of the spine measured on radiography, with the curve greater than 10 degrees (1). Among the different types of scoliosis, idiopathic type is the most common form (2). Also, idiopathic scoliosis depending on the age of onset is divided into three categories: Infantile, juvenile, and adolescent. In 89% of cases, idiopathic scoliosis begins in adolescence (3). One of the most common non-surgical treatments is the use of spinal braces, which has some advantages and disadvantages. Besides the benefits, the use of spinal braces has been reported to cause side effects such as respiratory problems, skin lesions, sleep disorders and psychosocial problems, which effect on Quality of Life (QoL) (4).

Milwaukee was the first brace widely accepted for the treatment of scoliosis (4). In the upper curves of the seventh vertebra, the brace regulates the development of the scoliosis curve, reduces the surgical rate, and improves balance on the sagittal plan by reconstructing the normal alignment of the spine

through external forces (5). The negative impact of the Milwaukee brace can be observed on QoL, especially in the psychological, sleep disorders, and body image domains (6). But the most important disadvantage of this brace is its appearance, which decrease its acceptance.

The most common criterion for evaluating the effectiveness of treatment in spinal deformities is the severity of spinal deviation (7), but this criterion is not necessarily the most important concern for patients and therapists (8). In fact, improving the QoL may be more essential for patients than other parameters (9). Therefore, one of the most important indicators in evaluating the treatment of adolescent idiopathic scoliosis (AIS) is the improvement of the QoL. Improving patients' QoL level is a multidimensional mental structure expressed as the "state of health." This structure includes disease and treatment in three main dimensions: physical, psychological, and social functioning (10). Therefore, evaluation and assessment of QoL can be significantly useful parameter for the evaluation of effectiveness of therapeutic interventions for individuals with AIS.

Studies have also shown that individuals' satisfaction with braces is directly related to the treatment process (11). A study by Haider *et al.* found that there was a significant association between the patients' satisfaction and the scoliosis treatment (12). Although researchers are aware of the psychological issues of scoliosis, little research has been carried out in this area. A retrospective study (2005) found that only 5 percent of studies related to scoliosis assessed a person's feeling of appearance (13). However, several other studies have ruled out the negative impact of braces on QoL (14-21), stating that braces have no effect on QoL (22-31). Although the differences may be due to differences in the type of brace, culture, patients' characteristics (32), failure to use accurate and using appropriate assessment tools in studies (13) and also how to answer the questionnaire by patients (29), but still how braces affect the people's QoL with AIS is being discussed (33). The QoL in individuals with AIS is often overlooked in assessing spinal deformities and the effectiveness of treatment (14, 19, 23, 34). However, in recent years, the use of mental measurements to complete the objective measurements of scoliosis is increasing (35-38).

Usually, measurement tools of QoL have a multidimensional structure which evaluates various factors related to physical, psychological, and social issues (39, 40). The first specialized questionnaire for assessing the patients' QoL with spinal deformities was designed in Spain named Quality of Life Profile for Spinal Disorders (QLPSD) by Clement *et al.* (41). The validity and reliability of this tool in Persian version were assessed by Motlagh *et al.* (42) who mentioned the questionnaire especially focused on "flexibility of the spine and chest" and "sleep" areas (43) which are major problems for patients using braces and neglected in other questionnaires. The aim of present study was to evaluate the effect of Milwaukee brace on the QoL using QLPSD questionnaire in patients with AIS.

Materials and Method

Participants

In this quasi experimental study, forty-two subjects with AIS were enrolled who referred to an orthotics and prosthetics center for receiving the Milwaukee brace in Tehran. The brace had been prescribed by a physician. Inclusion criteria were age between 10 to 20 years old (6, 18, 32), AIS patients with a curve of 20 to 45 degrees (47), and wearing Milwaukee braces for at least one month and maximum 6 months. Exclusion criteria were muscle strength of less than grade 3 in the trunk and shoulder, congenital scoliosis, scoliosis caused by Spina- bifida, Poliomyelitis, and Spondylolisthesis, and also people with a history of spinal cord

injury. The study was approved by the ethics committee of University of Social Welfare and Rehabilitation Science, and written informed consent was obtained from all patients.

Also, forty two patients who did not use brace or other interventions were matched in terms of age and the degree of curvature with the intervention group as the control group. Finally, present study, based on wearing brace or not, included two groups: intervention group (patients who were using Milwaukee brace) and control group (patients without any interventions).

Measurement tool

The semi-structured interview and the Persian version of the QLPSD questionnaire were used. QLPSD is a tool for measuring the health level of adolescents related to spinal deformities. This questionnaire is a valid and universal tool that shows reliable information about people's QoL, and physical and mental performance (41). This tool includes 21 questions in a form of 5 groups including psychosocial performance (7 questions), sleep disorders (4 questions), back pain (3 questions), self-image (4 questions), and flexibility of the spine (3 questions). The answer to the questions is based on a 5-point Likert scale (from completely agreeable to completely opposite). Thus, the score of each question is between 1 and 5 and the total range of numerical scores is between 21 and 105. The highest score indicates the lowest QoL and the lowest score indicates the highest QoL (41).

Statistical Analysis

Data were analyzed using SPSS statistical software version 24. The normality of the data was confirmed using the Kolmogorov-Smirnov test. An independent t-test was used to compare two groups (with and without brace). Also, Pearson correlation coefficient was used to assess the relationship between QoL and wearing the Milwaukee brace or not. The level of significance in $P=0.05$ was considered.

Results

Eighty-four patients with AIS who met the inclusion criteria were analyzed including 42 people in intervention group (using Milwaukee brace) and 42 in the control group (did not use any intervention). Patients' age and their curvature degree characterizing are shown in Table 1. Table 2 shows that the total score of QLPSD in the control and intervention group was 52.11 and 51.24, respectively, with a statistically significant increase ($P=0.015$) in bracing group compared with control group. So, the bracing intervention reduced the QoL in intervention group compared with control group.

Table 1. Mean (SD) of demographic variables of the subjects of two groups

Variables	Intervention group (n=42)	Control group (n=42)	P-value
Age	13.75 (1.186)	14.26 (2.194)	0.65
Cobb angle (degree)	28.8 (6.6)	29.3 (6.3)	0.73
Gender (female)	57%	48%	0.86

Table 2. Examination the QoL score and its dimensions in 2 groups

QoL	Intervention group	Control group	P-value
	Mean (SD)	Mean (SD)	
Psychosocial performance	19.09 (2.74)	12 (2.41)	0.003*
Sleep disorders	10.5 (4.05)	8.70 (1.6)	0.001*
Back pain	9.51 (1.40)	5.45 (1.42)	0.061
Self-image	16.05 (2.61)	11.43 (1.08)	0.016*
Flexibility of the spine	11.82 (3.20)	9.54 (1.20)	0.018*
Total	51.24 (10.45)	52.11 (5.02)	0.015*

Quality of life (QoL), *: $P < 0.05$ **Table 3.** The relationship between QoL dimensions with the wearing the Milwaukee brace or not in two groups

	Intervention group		Control group	
	r coefficient	P-value	r coefficient	P-value
Psychosocial performance	0.35	0.002*	-0.601	0.002*
Sleep disorders	0.71	0.001*	-0.450	0.001*
Back pain	-0.32	0.003*	-0.051	0.003*
Self-image	0.065	0.018*	-0.011	0.018*
Flexibility of spine	0.0152	0.016*	-0.201	0.0152*
Total	0.21	0.004*	-0.341	0.078

Quality of life (QoL), *: $P < 0.05$

Regarding the dimensions of QLPSD questionnaire, the psychosocial performance ($P=0.003$), sleep disorders ($P=0.001$), self-image ($P=0.016$), and the flexibility of the spine ($P=0.018$) were statistically increased in the intervention group in comparison of the control group. The difference in back pain between two groups was not significant ($P=0.061$) (Table 1).

According to Table 3, the total score of QoL and all its dimensions in the intervention group showed that the differences were statistically significant ($P=0.004$). What in examining these two variables is important is the direction of correlation. In examining the relationship, the overall score of QLPSD in both groups was considered. The sign of the correlation coefficient total QLPSD in the control group was negative, while it was positive in the intervention group which indicated a lower QoL by wearing a Milwaukee brace.

Examination of the dimensions of QLPSD in the control group, in all aspects of QLPSD, was negative that indicated the QLPSD score in these dimensions did not change. However, the correlation coefficient in terms of psychosocial performance, sleep disorders, self-esteem, and flexibility of the spine in the intervention group was positive, which showed the QoL was changed. So, the results indicated that subjects who used the Milwaukee brace had a lower QoL. However, the correlation coefficient for back pain parameter in the intervention group was negative and it can be concluded that no change was occurred in this dimension.

Discussion

Milwaukee brace is one of the most common braces as a non-surgical treatment of AIS. Despite the effectiveness of this brace, some difficulties have been reported while wearing it, which can negatively affect the QoL of patients. The aim of this study was to compare the QoL parameter using the QLPSD questionnaire with Milwaukee braced and unbraced conditions in patients with AIS.

The results of present study revealed a statistically significant decrease in QoL score in the intervention group compared to the control group ($p = 0.015$). Mental performance and self-image are two important dimensions of a person's psychological aspects, and sleep disorders, back pain and spinal flexibility are the individual's physical aspects. This section discusses about the comparison of each dimension of QLPSD questionnaire in the two groups studied.

Investigating the psychological aspects (mental performance and self-image)

Bracing effect on QoL is a controversial topic for many researchers. Many studies have shown that the use of braces may reduce a person's QoL (41, 46-49). The results of the present study also showed that wearing the Milwaukee brace reduced people's QoL with AIS. This result was in line with Friedel's (47), Fastrom's (46), and Saponzi's (48) studies. However, Agonalli *et al* found that

wearing braces did not reduce the QoL of school-age adolescent (29). In Agonalli's study, the questionnaires assessing the QoL were completed by the parents of the patients, while the questionnaire was completed by the patients themselves in present study. It seems this is a possible reason for difference between two studies, since patients' perceptions of deformity, functional limitations, social relationships, and the conditions in which they struggle may be very different from their parents' perceptions.

Based on the literature, one of the most important aspects of QoL affected by using brace is the psychological dimension of individuals (46, 48). The results of present study indicated that psychological performance score of QLPSD significantly was increased (7.09 %) in Milwaukee group in comparison of the control group which showed a lower psychological performance. In this regard, Clement *et al.* stated that wearing braces dramatically affected the psychological function of scoliotic individuals, but the type of brace did not mention (41).

By comparing the self-image parameter in the two groups, a statistically significant difference was observed between the intervention and control groups. This means that the bracing treatment resulted in an increase in self-image score (4.62%). Many studies have shown that spinal deviations have a significant negative effect on self-image (50-52). In addition to the deviation itself, the type of treatment used also may affect this feeling. Spuntzi *et al.* also confirmed the similar result (48). However, the results of a study did not report a negative effect of brace on the self-image in AIS patients using the Boston brace (53).

Physical aspect (sleep disorders, back pain, spinal flexibility)

Sleep disorders, back pain, and spinal flexibility are important physical aspects of QoL which can be affected by wearing braces (41). In the present study, by comparing the mean score of sleep disorders level between two groups, the rate of sleep disorders in intervention group wearing the Milwaukee brace was significantly higher than the control group without any interventions. Some of the effective factors in causing sleep disorders in adolescents undergoing brace treatment are psychological problems and the structure of orthoses used (54). Kroussis *et al.* assessed the patients' QoL with scoliosis and hyper kyphosis with the tool "Assessing the QoL in spinal deformities" and the results showed that sleep disorders may be due to feeling of shame (54). Another study indicated a negative effect of bracing on sleep item in people with AIS (18).

By comparing the level of back pain between the two groups, there was no statistically significant difference in the present study. This result is in line with Haifley's study. Heifli *et al.* reported no significant difference in pain level between two groups (brace and no brace) (24). A possible explanation for back

pain could be that wearing brace, may reduce the muscle mass and strength, and increase the pressure on the intervertebral disc, ligaments, and facets. These side effects may cause back pain. Therefore, according to the mentioned side effects, muscle strengthening exercises are recommended during brace treatment and it should be investigated in the future study (54).

The results indicated there was a significant difference in spinal flexibility between the two groups. This parameter was higher in the Milwaukee group (2.28%), which indicates a greater limitation created by Milwaukee brace for people with AIS. Kliment *et al.* stated that reduction in spinal flexibility by the Milwaukee brace was even greater than that of other thoracolumbar braces (6). The cause of the negative impact of Milwaukee brace on spinal flexibility can be considered to be related to its structure. Spinal column is surrounded by the cervical ring and pelvic corset (as the upper and lower points) of Milwaukee brace, which it can cause reducing the amount of spinal movement and flexibility (55).

Present study just evaluated the effect of one type of scoliosis braces. Also, the Milwaukee Brace was made by different orthotist. The comparison of different types of braces in a long-term follow-up on QoL is suggested in the future study. Also, an orthotic treatment program along strengthening spinal muscles and psychology interventions is recommended whether they can improve QoL.

Conclusion

The Milwaukee brace decreased QoL level in individuals with AIS. Milwaukee has a negative effect on psychological performance, sleep disorders, self-image, and spinal flexibility. Due to the effective role of QoL on the treatment process, the Milwaukee braces should be prescribed cautiously in people with idiopathic scoliosis.

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