

Changes in Quality of Life among Patients with Chronic Low Back Pain in the Iranian Traditional Medicine Clinics

Maryam Baradaran-Binazir ^{*1}, Fatemeh Ranjbar-Oskoui ¹,
Seyyed Mohammadbagher Fazljou ², Delara Laghousi ¹

1. Social Determinants of Health Research Center, Health Management and Safety Promotion Research Institute, Tabriz University of Medical Sciences, Tabriz, Iran
2. Department of Persian Medicine, Faculty of Traditional Medicine, Tabriz University of Medical Sciences, Tabriz, Iran

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Corresponding Author:

Maryam Baradaran-Binazir

maryam_baradaran@hotmail.com

ABSTRACT

Background: Chronic low back pain (CLBP) is regarded as one of the most frequent and costly conditions which can affect patients' quality of life. The current study aims to investigate changes in quality of life among patients with CLBP.

Methods: Prospective observational study was performed from December 2021 to February 2022 in Baharan, Sina and Asadabadi traditional medicine clinics, Tabriz, Iran. Patients were recruited using a convenience sampling method, who were aged 20 years or older and had low back pain symptoms for 12 weeks or more. Data were collected at baseline, one month and two month follow-up by interviewing the patients. The study tool was Short Form Health Survey (SF-12) questionnaire.

Results: Out of 210 participants, 62.4% (131) were female. The change in mean score of life quality at the baseline, one- month and two-month follow-up was 23.76, 35.08 and 40.11, respectively ($P = 0.0001$). There were significant changes in all eight dimensions of life quality ($P = 0.0001$). Additionally, younger Patients ($50 \geq$) had 1.35 scores of life quality higher than older patients ($P = 0.021$). Retired, self-employed, housewife and unemployed patients had 6.41, 4.68, 4.18 and 5.38 scores of quality of life lower than office workers, subsequently ($P = 0.001$). Furthermore, illiterate patients, patients with primary and high school educations had 5.76, 2.61 and 1.33 scores of quality of life less than patients with university degree ($p < 0.05$).

Conclusion: ITM treatment method could contain several effects on the dimensions of quality of life among patients with CLBP. More detailed investigation is required to achieve greater accuracy.

Keywords: low back pain, medicine, traditional, quality of life

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Introduction

CLBP is one of the most frequent and costly diseases worldwide (1). The economic damages of this problem affect both the individual and society (2). According to the World Health Organization (WHO), the ageing population is expected to lead to an increase in the prevalence and concern about CLBP in various communities (1). In Iran, the prevalence of CLBP has actually increased in recent years and the predicted lifetime prevalence of CLBP was 51% (CI 95%: 40.1-61.8) (3).

CLBP is responsible for the excessive use of diagnostic evaluations and health care managements, and is a focus of the WHO (1). Almost all CLBP patients benefit from medication, mostly non-steroidal anti-inflammatory drugs (NSAIDs) to reduce pain and improve their competence to return to normal function as soon as possible (4). The consequences of long-term use of NSAIDs are concerning, therefore a large number of CLBP patients should minimize the use of NSAIDs just as required basis (5). Several patients with chronic diseases generally concentrate on complementary and alternative medicine (CAM), instead of conventional treatment or along with, as supplementary (6). CAM is typically associated with any remedial treatment that does not belong into the category of conventional medical treatment and illustrates a considerable and diverse collection of therapies shaped by different health theories and concepts (7).

The National Centre for Complementary and Integrative Health provides an explicit definition of CAM as a collection of different medical methods, and procedures that are not normally regarded as part of conventional medicine (6). Traditional Chinese medicine (TCM), Iranian traditional medicine (ITM), naturopathy, chiropractic, acupuncture, vegetative products, and massage are examples of CAM (7). It is commonly reported that the use of CAM has been increasing in developing countries (8). In addition to investigations in the United States and European countries, several studies have investigated the use of CAM in Asian countries, containing China and Iran (6). The Popularity of utilizing CAM therapies is reported to be 34% in the United Kingdom, 35% in the USA,

49% in France and 46% in Australia (9). In a study conducted by Ghaedi et al. in Iran, the popularity of applying CAM for chronic diseases was 75.4% (10). Iranian traditional medicine (ITM) is one of the oldest patterns of CAM (9). The use of ITM was strongly associated with the chronic diseases such as musculoskeletal disorders (11). Moreover, CAM use is increasing in Australia, Europe, and North America. Regarding the overall trend of CAM use, it is believed that most patients with CLBP will try CAM (6). On the basis of our knowledge, there is no previous information accessible on the use of ITM for CLBP in patients in Iran. Therefore, it is important to explore its effects and possible factors influencing the use of ITM treatment in this population.

CLBP can have a significant impact on the patients' quality of life (QOL). There is a certain concern among the CLBP patients considering the preservation of QOL (12). The patients with CLBP suffer from continuous pain and impairment at some periods of their life and reveal severe deterioration in their QOL (6). Several investigations have attempted to describe the determinants influencing QOL in patients with CLBP (12). Namiranian et al. reported that the Iranian Traditional Massage was as good as acupuncture and physiotherapy in reducing trouble and impairment in CLBP patients (13). The other identical study demonstrated Persian manual therapy method for chronic low-back pain was a useful and practical method for the management of LBP (14). Although mentioned studies have evaluated ITM, they have only investigated one therapeutic method for the management of patients. Therefore, an exploration of the interventions and treatment programs, such as ITM, that lead to worse or better quality of life in this diagnostic group will help to add the existing scientific literature. Furthermore, in order to design and test future interventions to improve the quality of life among patients with CLBP, it is essential to know the major determinants to contribute to their quality of life. Therefore, the current study aims to investigate the changes in the life quality among patients with CLBP in the Iranian traditional medicine clinics

during a 2-month follow-up study.

Methods

Study design and sample

A perspective study with no control group was performed from December 2021 to February 2022 in Tabriz, East Azarbaijan province, Iran. There were three clinics selected in the study by a convenience sampling method: Baharan, Sina and Asadabadi traditional medicine clinics. These clinics had the following inclusion criteria 1) Covered both urban and rural areas of East Azarbaijan province and 2) Currently providing health care services based on the traditional medicine guidelines. For CLBP patients according to their conditions, traditional medicine methods were Fasd (bloodletting), cupping/ hijamat, leech therapy and medicinal plants included Aloe vera, Rosemary and Ginger. CLBP defined as a pain lasting for at least 12 weeks and in adults older than 20 years was higher than younger aged group (15). Therefore, patients included in the investigation, who had the following criteria 1) Aged 20 years or older 2) suffered from low back pain symptoms for 12 weeks or more 3) were currently receiving CLBP services at one of the afore mentioned clinics during the time of the study 4) were physically and psychologically capable to answer questions from the interviewers 5) Provided informed consent to a member of the study team present at one of the study sites. Furthermore, patients using palliative drugs, physiotherapy and corrective exercises, acupuncture or resting at home, patients with musculoskeletal anomalies, allergy to herbal drugs, vertebral fractures, tumors or infections were excluded.

A convenience sampling approach was utilized to enroll participants from the selected clinics. Participants were invited to attend in the study at the baseline, one- month and two-month follow-up. The sample size was calculated by using G*Power software (general power analysis) version 3.1., precision targeting of 0.05 standard deviation and 80 % power based on the mean quality of life changes (13.34 with standard deviation of 6.12) from a study by Tavafian (14), generating 185

individuals. Furthermore, 28 (15 %) were included to determine the possibility of some patients dropping out of the study. The ultimate calculated sample size was 213.

Questionnaire

To assess the life quality of participants, the Short Form Health Survey (SF-12) questionnaire was applied. The SF-12 as a briefer substitute for the SF-36 is broadly utilized in health sciences investigations. Montazeri and his colleagues evaluated the validity and reliability of the Persian version of SF-12. Mainly, the results of the mentioned investigation recommended that the SF-12 is a reliable and valid instrument for health associated quality of life in Iran (17). Cronbach's alpha for Physical Component Summary and the Mental Component Summary was 0.73 and 0.72, respectively. Additionally, the principal component analysis demonstrated that a two-factor structure together explained approximately 60% of the variance. The confirmatory factor analysis revealed an appropriate fit to the data for the mentioned factors (15). The SF-12 contains 12 questions pertaining to 8 dimensions (General health perceptions, Limitations in usual role activities due to physical health problems, Limitations in physical activities because of health problems, Limitations in usual role activities with regard to emotional problems, Bodily pain, Limitations in social activities because of physical or emotional problems, Vitality and General mental health). The SF-12 scale is graded using Likert's method of summated scores (17). In this method, a score is assigned to each item response category, for instance in the general health perception dimension 5, 4, 3, 2, 1 for excellent, very good, good, fair, poor responses, respectively, or in the limitations in usual role activities due to physical health problems dimension 1, 2, 3 for yes very limited, yes limited a little, no not at all responses, respectively and so on. The questionnaire score is then calculated by adding the scores assigned to item responses. The maximum score obtained for the whole questionnaire is 48 and the minimum score is 12, with a higher score uncovering an

improved health condition. In order to interpret the level of classification, the values of 12-24, 25-36, and 37-48 were equivalent to three classifications of good, average, and poor, respectively. The validity and reliability of this questionnaire were previously confirmed in Iran (17). Data collection was performed by interviewing with the patients.

Statistical analysis

Categorical and continuous variables were described as percentages and mean (SD), respectively. Friedman test was applied to determine differences in mean scores of SF12 questionnaire scores at the baseline, one- month and two-month follow-up times. In addition, Friedman test was used to compare the mean scores of all eight dimensions of quality of life at all three points of time. To test the differences in the mean scores of dimensions of life quality at all three points of time in a continuous matched pair of data Wilcoxon Signed-Rank Test was used. To investigate the factors associated with change in the quality of life in patients with low back pain, GEE with Matrix covariance structure and exchangeability estimation method for exchangeable covariance matrix was applied. GEE

is a common analytical approach to conform marginal models for longitudinal data in follow up studies (18). For the two-month follow-up variable with missing data, we imputed values using multiple imputation by chained equation techniques by first creating ten copies of the dataset and then fitting multiple logistic regression models to the imputed datasets. The significance level was set at $p < 0.05$. All analyses were performed using IBM SPSS statistics version 24 software.

Results

In the current survey, a total of 218 patients with CLBP were participated. On the whole 8 SF-12 questionnaires were not fulfilled; therefore, they failed to be analyzed. Out of 210 participants, 62.4% (131) were female and 37.6% (79) were male. The mean age of the patients was 43.8 ± 11.2 years. The baseline characteristics of patients were demonstrated in Table 1.

The mean score of life quality at the baseline, one- month and two-month follow-up was 23.76, 35.08 and 40.11, respectively. The change in QoL of participants was presented in Table 2. The change was statistically significant.

Table 1. Baseline characteristics in the study sample (n = 210)

Characteristics	Frequency (%)
Age	
50 \geq	140 (66.7)
50 <	70 (33.3)
Gender	
Male	79 (37.6)
Female	131 (62.4)
Occupation	
Retired	58 (27.6)
Self-employed	63 (30.2)
Housewife Unemployed	51 (24.2)
Office worker	27 (12.8)
	11 (5.2)
Education level	
Illiterate	13 (6.2)
Primary (grade 1-6)	72 (34.3)
High (grade 6-12)	67 (31.9)
University degree	58 (27.6)
Marital status	
Single	21 (10)
Married	180 (85.7)
Divorced	5 (2.3)
Widow(er)	4 (2)

Table 2. Changes in quality of life score among participant

Time point	Quality of Life Score			P-value *
	Mean (SD)	Maximum	Minimum	
baseline	23.76 (6.54)	42	12	0.0001
one- month follow up	35.08 (7.42)	48	12	0.0001
two-month follow up	40.11 (3.83)	48	23	0.0001

* Friedman test was used.

There were significant changes in all eight dimensions of life quality measured by SF-12 (Table 3). Comparison of mean scores of all eight

dimensions of life quality at all three points of time were statistically significant, different and had increasing trends (Table 3).

Table 3. Changes in dimensions of quality of life score measured by SF-12 among participant

Dimensions of quality of life (max-min score)	Baseline mean (SD)	One- month follow up mean (SD)	Two-month follow up mean (SD)	P-value *
General health perceptions (1-5)	1.52 (0.62)	2.45 (1.02)	3.01 (1.08)	0.0001
Limitations in usual role activities because of physical health problems (2-6)	3.15 (1.24)	4.52 (1.27)	5.11 (0.91)	0.0001
Limitations in physical activities because of health problems (2-4)	2.46 (0.53)	3.37 (0.63)	3.62 (0.52)	0.0001
Limitations in usual role activities because of emotional problems (2-4)	2.68 (0.76)	3.72 (0.59)	5.81 (1.06)	0.0001
Bodily pain (1-5)	2.11 (0.78)	3.49 (1.02)	3.86 (0.91)	0.0001
Limitations in social activities because of physical or emotional problems (1-6)	3.01 (1.31)	4.45 (1.26)	4.49 (1.01)	0.0001
Vitality (1-6)	2.59 (0.92)	3.82 (1.02)	4.98 (0.96)	0.0001
General mental health (2-12)	6.25 (1.93)	8.71 (1.87)	9.56 (1.58)	0.0001

* Friedman test was used.

Additionally, the Wilcoxon Signed-Rank Test for testing the mean scores of the dimensions of quality of life at all three time points in a continuous

matched pair of data was statistically significant even after correction with the Bonferroni method for multiple comparisons (Table 4).

Table 4. P values for differences in the mean scores of dimensions of quality of life at all three points of time in a continuous matched pair of data

Dimensions of quality of life	Baseline- One month	Baseline- Two month	One month- Two month
General health perceptions	0.0001	0.0001	0.0001
Limitations in usual role activities because of physical health problems	0.0001	0.0001	0.0001
Limitations in physical activities because of health problems	0.0001	0.0001	0.0001
Limitations in usual role activities because of emotional problems	0.0001	0.0001	0.0001
Bodily pain	0.0001	0.0001	0.0001
Limitations in social activities because of physical or emotional problems	0.0001	0.0001	0.0001
Vitality	0.0001	0.0001	0.0001
General mental health	0.0001	0.0001	0.0001

Factors associated with participants' quality of life of were described in Table 5. The associations of age, occupation and education level with quality of life in a sample of patients with chronic low back pain were statistically significant. On average, younger patients ($50 \geq$) had 1.35 quality

of life scores more than older patients ($p = 0.021$). In term of occupation, retired patients had 6.41 quality of life scores less than patients with other job ($p = 0.001$). Additionally, Illiterate patients had 5.76 quality of life scores less than patients with other education levels ($p = 0.0001$).

Table 5. Factors associated with quality of life among participant using GEE* method

Factors	Beta (95% CI)	P-value*
Age		
50 \geq	1.35 (0.21to2.50)	0.021
50 <	Reference	
Occupation		
Retired	-6.41 (-11.03 to- 1.79)	0.001
Self-employed	-4.68 (-9.27to -0.08)	0.001
Housewife	-4.18 (-9.29to-0.39)	0.001
Unemployed	-5.38 (-7.11to-0.62)	0.001
Office worker	Reference	
Education level		
Illiterate	-5.76 (-8.24 to -3.28)	0.0001
Primary (grade 1-6)	-2.61 (-3.11 to -1.41)	0.0001
High (grade 6-12)	-1.33 (-2.66 to 0.003)	0.051
University degree	Reference	

* Generalized Estimating Equation.

Discussion

The results demonstrated that the mean score of quality of life among patients with CLBP increased from 23.76 to 40.11 during two months. In consistent with present study, Won-Suk Sung et al, documented the efficacy and safety of the complementary and alternative medicine for the management of CLBP (19). The other identical study suggested that treating CLBP with complementary and alternative medicine was safe and effective in the short-term (20). Regarding the complications of using chemical pain relief drugs and less adverse or unpleasant effects of treatment with complementary and alternative medicine for the management of CLBP, in addition to the effectiveness of complementary and alternative medicine for CLBP, it has extensively been used (11).

In present study, four remedial methods containing Fasd (bloodletting), cupping/hijamat, leech therapy and medicinal plants was observed which including Aloe vera, Rosemary and Ginger were applied for treatment of CLBP in the

traditional medicine clinics.

Farhadi et al evaluated the efficacy of one of the remedial methods (wet-cupping) for treating CLBP. It was safe and acceptable to patients which were proved by them (21). The identical study assessed the effect of the other remedial method (leech therapy) and reported that it was more effective in reducing the pain intensity and in improving quality of life in the short term (22). Maybe their consistency with our study was due to similar setting and study population.

Fasd or Phlebotomy is one of the depletion methods used in ITM. This method results in the discharge of body substances that cause harm, for instance, when some chemical compounds containing soda substance induces backache, its treatment is done by phlebotomy (23). Cupping is a remedial method as an old treatment method from complementary medicine and alternative, which has approximately been represented in all cultures. It is believed that cupping has worked in a comparable form as acupuncture: cupping may stimulate peripheral nerves system or the sense

organs (11). The leech was utilized for various diseases in thousands of years ago (24). Painkiller effects of leech therapy in other studies has been approved for patients with osteoarthritis while it was reported that therapy by the leech have more effects than applying diclofenac and have lesser harm effects (25). Aloe Vera is a medicinal plant. The painkiller impacts and reducing inflammation in the Aloe Vera is associated with hydrolyzing enzyme for quinine and prostaglandin (11). Rosemary bears numerous pharmacological effects, containing antioxidant effects, stimulation of peripheral nerves. Furthermore, antimicrobial activity and pain relief for this plant have been reported (26). And ultimately, Ginger is extensively applied for different medication plans; one of which is painkiller (11).

This study manifested that the traditional medicine methods improved significantly on all quality of life dimensions. The other study which assessed a brief outpatient programs' effects on the quality of life among patients with CLBP demonstrated that the program is an effective intervention and might improve the life quality over a period of 3 months in patients with CLBP (26). While in the mentioned study, improvements were exclusively observed on the bodily pain, vitality and mental health dimensions (26). The ability of the traditional medicine methods to result in significant improvements on all life quality dimensions for its patients, in contrast to the other studies, demonstrated the likely advantage of the traditional medicine in these areas. In contrast to previous studies (27, 28) we proved that the traditional medicine was effective in both improving patients' physical functioning and mental component of patients' life quality. A recent study on the subject matter has revealed that the health related to life quality of patients with CLBP depended on functional condition and emotional determinants more than simple physical factors (28). Therefore, in this way it seems that the traditional medicine is a very relevant strategy to improve both patients' physical and psychological status (6).

An important feature of the traditional medicine

was the highly significant improvement in the all subscale scores. These were much more pronounced in the traditional medicine than in other studies (27, 28), and analysis exhibited that the mean differences in improvement at all three points of time were significant.

The improvement in all quality of life scales could be related to these factors: firstly, the reduction in physical pain, which facilitated the accomplishment of routine activities, and secondly, reducing the risk of impairment due to the use of healing ways and medicinal herbs to have a safer method to treat CLBP (16). The most obviously, one of the aims of traditional medicine is to return the patients to the maximum desirable level of capacity (12). Actually improving performance and decreasing impairment risk are key elements in attaining this goal. Diminishing the risk of disability indicates that the traditional medicine have a positive impact by pain relieving effect of its components (11).

In this study, we investigated the associations of age, occupation and education level with quality of life in a sample of patients with chronic low back pain at the baseline, one- month and two-month follow-up in the traditional medicine clinics. We observed a significant association between age and occupation with quality of life at all three points of time. Younger patients had better quality of life than older ones. Elderly individuals with low back pain had low adherence to the treatment program which may lead to decrease in quality of life score among patients (29). Furthermore, age was significantly related to social and leisure activities, with the highest activity engagement in the younger 50years old and lower levels in the older age groups (30). Most retired patients were older than 50 years old. Moreover, household activity engagement was lower in older patients (30). A lower quality of life was proved among retired, self-employed, housewife and unemployed compared with office workers. Similarly, the effect of age and occupation on well-being outcomes was in favor of the younger patients: With advancing age, anxiety, depression, and affective distress levels were higher. Our results are not consistent

with the “well-being paradox”, which explains that although older people face with mental and physical impairments likewise other trouble encounters and a higher risk of restrictions, well-being fails inevitably to decline with advancing age (30).

In our study, patients with higher level of education had higher quality of life at the baseline, one- month and two-month follow-up in the traditional medicine clinics. Education level has been unveiled to influence adherence to exercise plans among individuals with CLBP (31). In other studies, it was demonstrated that CLBP severity and education level was related, those with high education level are more likely to be active which lead to experience less pain than others (29).

Our study had a fundamental strength. We performed follow up study and interviewed with the patients at the baseline, one- month and two-month follow-up times on the patients with CLBP. Nevertheless, our study included several limitations: we applied convenient sampling way which could cause selection bias. Additionally, we refused to evaluate patients’ low back pain severity. Furthermore, our setting was the traditional medicine clinics and including patients from other clinics as a control group was not available to us, so a perspective study with no control group was conducted and in order to have less bias, we excluded patients with other treatments. Finally, for CLBP patients based on their conditions, various traditional medicine methods were used while our study failed to assess the effectiveness of the treatment methods one by one. Hence, it seems difficult to judge the effectiveness of traditional medicine treatment plans, separately.

Conclusion

The ITM treatment method could have some effects on all eight dimensions of quality of life measured by the SF-12 among patients with CLBP. The mean score of life quality at the baseline, one-month and two-month follow-up was increased. To be more accurate, more investigation is required in the details, with longer follow up period and with a control group.

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Conflict of interest

All authors declare no conflict of interest.

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Ethical Considerations

We respected the autonomy of patients and protected their anonymity.

Code of Ethics

This study was approved by the Ethics Committee of Tabriz University of Medical Sciences (IR.TBZMED.REC.1397.947).

Authors’ Contribution

All authors equally contributed to preparing this paper.

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