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Effects of an Herbal Medicine on Relieving Disability and Pain due to Chronic Low Back Pain (LBP)

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ABSTRACT: Low back pain (LBP) is one of the most common health problems in the world population which has a significant effect on quality of life. *Mentha longifolia* which is known for its various therapeutic effects such as analgesic and anti-inflammatory, has been used as an herbal treatment in Iranian traditional medicine (ITM). Regarding the unpleasant side effects of current available medications, we aimed to evaluate the efficacy of *M. longifolia* on relieving pain and disability symptoms in patients suffering from LBP.

Key words: Back pain, plants, herb, traditional medicine

INTRODUCTION

Low back pain (LBP) is one of the most common health problems in the world population (Cassidy *et al.,* 2005), which has a significant effect on quality of life (Hong *et al.,* 2014). About 70-85% of general population experienced LBP in some point of their lives (Hong *et al.,* 2014). It causes significant disability, prolonged loss of function, work absence, and treatment costs, which imposes an excessive economical burden on society (Cassidy *et al.,* 2005; Last and Hulbert, 2009).

Despite advances in medical knowledge, many cases of LBP are inadequately treated. This might be due to medication side effects, and increased numeral co-morbidities that prevent surgical interventions (Morone *et al.,* 2008). The previous studies showed that complementary and alternative medicine (CAM) interventions were suggested for treatments of LBP in the general population (Wang et al., 2005). In the recent years, the World Health Organization of the United Nations (WHO) has revived CAM for the development of native knowledge (Ameri *et al.,* 2014); and in the United States more than one-third of population applies CAM therapies (Wang *et al.,* 2005). Traditional Iranian medicine (TIM), with more than 4000 years of history, consists of the sum total of all the knowledge and practices used in diagnosis, prevention and exclusion in Iran from ancient times to the present (Avicenna, 1593; Heydarirad and Choopani, 2014;). TIM has potential to solve many health problems(Mozaffarpur *et al,* 2012; Alijaniha *et al,* 2015). In TIM manuscripts, LBP is described in the title of "vajae zahr"; and variable remedies used as painkiller, and anti-inflammatory which "*M. longifolia*" is one of them (Avicenna, 1593; Beketov *et al.,* 2005). There were no studies found regarding the effect of *M. longifolia* on LBP. The aim of the current study was to examine the effect of *M. longifolia* on improvement LBP before and after clinical trial.

MATERIALS AND METHODS

A. Plant material and analysis of the prepared medicine

Dried *M. longifolia* were collected from drugs market in Tehran and was kept at the Herbarium of Shahid Beheshti University of Medical sciences (Sbum 1028).

The medicine was prepared in 500 mg capsules containing 250 mg of the aqueous extract of *M. longifolia* and 250 mg starch as filler

Total phenolic content of *M. longifolia* capsules was determined by folin-ciocalteu method; also, the flavonoid content was measured using spectrophotometric method according to Beketov *et al.* (Beketov *et al.,* 2005).

B. Selection of patients and treatment assessment

This study was conducted as a before/after clinical trial at clinic School of Traditional Medicine, Shahed University of Medical Sciences to assess the efficacy of *M. longifolia* in the treatment of LBP.

The study was approved by the local research ethics committees, and registered in the Iranian registry of clinical trials. All the participants were informed about the study, and obtained a written informed consent, before their participation in the study.

Thirty patients aged between 20-55 years, with LBP for more than 3 months, examined by neurosurgeon were eligible, and received *M. longifolia* capsules for 28 days. According to design of the study, patients should take one capsule after each meal.

If there were any indication for surgery, suspicion for malignancy, history of trauma, or chronic infection, use of steroids, pregnancy, and breast-feeding; patients were excluded from the study.

C. Follow-up patients

The duration of this study was 8 weeks. The patients were used experimental drug for 4 weeks and examined by the investigator before intervention and in 2, 4. 8 weeks after intervention. In the present study quality of life (QOL) was assessed through the "SF36 questionnaire" which divided quality of life to 3 classes: Unpleasant(less than 50), Moderate (between 50-75), Pleasant (more than 76), disability from LBP was measured by "Oswestry questionnaire", which evaluate the level of patient's functional level in 10 parts; total score of 10 parts, as a fraction of 50 (the highest score) multiplied by 100, was appraised as an overall percentage score. Patients were divided into the five classes: including mild (0-20%), moderate (21-40%), severe (41-60%), crippled (61-80%) and bed bound (81-100%) numerical scale was used to assess pain. In this method, pain intensity was measured with a 10-cmtape, that divided into four groups no pain (0), mild (1), moderate (4-6) and severe (10).

D. Statistical analysis

To compare QOL score, disability, and pain in 0, 2, 4 and 8 weeks of study. Friedman non-parametric test was used. The data were analyzed using SPSS ver.18 and significance level (P= 0.05) was considered.

RESULTS

Thirty seven patients based on their entry criteria were enrolled to the study.

Thirty patients used the experimental drugs by the end of study, and the results were analyzed, while seven patients did not use the experimental medicine (five of them because of the heartburn, and two patients stated that the experimental medicine didn't have effect).

The mean age of the patients was 40.4 ± 8.4, which 56.7% of them were males. Most of the group's BMI were ranged between 25 and 29.9 and the mean was 27.5 ± 2.7.

At the beginning of the study only 53. 3% of patient had moderate disability and 46.7% belonged to sever and crippled groups. At the end of 4 week about 70% of patients had moderate disability and this result remained stable until 8 week that represents a decrease in the rate of severe, and crippled groups.

The results of study showed a significant difference for pain and disability of the patients in before and the end of the study (P = 0.001; Table 1; Table 2). Also, results showed that QOL had a significant difference before and after study (P = 0.005; Table 3).

Table 1: Functional Disability (Oswestry Disability Index) for the Chronic Low back pain.

Time		Pre	2WKS	4WKS	8WKS
The number of patient		30	30	30	30
Relative Frequency Percentage of functional disability	MILD	0	0	0	0
	MODERATE	53.3	73.3	73.3	70.0
	SEVERE	40.0	23.3	26.7	30.0
	CRIPPLED	6.7	3.3	0	0
	BED-BOUND	0	0	0	0
mean±SD		42.5±10.1	37.3±10.3.	36.9±9.9	36.4±9.8
Friedman's nonparametric test		0.001			

SD: Standard deviation, 30 patient in clinical trial with Chronic Low back pain who used *M. longifolia* for 4 wks Values are expressed as mean (95% confidence interval). Friedman's non parametric test was used, and the results indicated that the scale had a statistically significant difference (P = 0.001)

Table 2: Severity of pain (NRS) in patient with Chronic Low back pain.

Time		**Pre**	**2wks**	**4wks**	**8wks**
The number of patient		30	30	30	30
Relative Frequency Percentage of Severity of pain	NO PAIN	0	0	0	0
	MILD	0	16.7	23.3	26.7
	MODERATE	80.0	76.7	73.3	73.3
	SEVERE	20.0	6.7	3.3	0
mean±SD		5.5±1.1	4.7±1.14	4.5±1.2	4.4±1.12
Friedman's nonparametric test		0.001			

SD: Standard deviation, 30 patient in clinical trial with Chronic Low back pain who used *M. longifolia for 4 wks* Values are expressed as mean (95% confidence interval). Friedman's nonparametric test was used, and the results indicated that the scale had a statistically significant difference (P = 0.001)

Table 3: Quality of life in patient with Chronic Low back pain.

Time		Pre	8wks
The number of patient		30	30
Relative Frequency Percentage	Unpleasant	46.7	40.0
	Moderate	53.3	60.0
	Pleasant	0	0
SD±mean		32.5±20.9	39.17±14.20
Friedman's non parametric test		0.005	

SD: Standard deviation, 30 patient in clinical trial with Chronic Low back pain who used *M. longifolia for 4 wks* Values are expressed as mean (95% confidence interval). Friedman's non parametric test was used, and the results indicated that the scale had a statistically significant difference (P = 0.001).

DISCUSSION

LBP is scarcely fatal but deeply affects functioning, so there are significant implications for the QOL of these patients (Morone *et al.,* 2008). Studies demonstrate that CAM interventions can help to improvement of LBP in the general population (Chrubasik *et al.,* 2001; Wang *et al.,* 2005; Chrubasik *et al.,* 2010; da Silva *et al.,* 2010; Mathie *et al.,* 2013).

The results of our study show that *M. longifolia* can have a relieving effect on LBP. Generally, there was a remarkable reduction in pain at the end of the study; which was in accordance with previous studies that were done with other herbal medicine (Chrubasik *et al.,* 2001; Yip and Tse, 2004; Chrubasik *et al.,* 2010; da Silva *et al.,* 2010; Mathie *et al.,* 2013); also, it was predictable in TIM (because the analgesic effect of this herb was emphasized frequently in the Iranian manuscripts) (Khorasani, 2001).As for new investigations, the mechanism of pain reduction is due to phenols and flavonoids contents of *M. longifolia*; these contents also provide anti-inflammatory effects which is effective in reducing pain (Gulluce *et al.,* 2007). In addition, in this study *M. longifolia* had a significant effect on improving disability, while to the best of our knowledge, pervious herbal studies did not evaluated this subject; however it is obvious that reducing the pain causes reducing LBP-induced-disability, and these two factors (pain and disability) will improve the QOL. The results of this study, which indicated that QOL was improved significantly at the end of study, conformed this subject. The intervention in this study did not have any serious side effects. Although five patients reported heartburn. Since heart burn is a condition which many factors such as diet, host physiological and environmental factors can affect on it (Polat and Polat, 2012), so in this study heartburn might have another reasons; thus, further studies should be done to investigate this subject. The present study supports the efficacy of *M. longifolia* on reducing of pain and disability and improving QOL.

However, due to the small size of the study population of our experimental therapy, reliability of the results might have been affected, that is suggesting further studies with larger sample size to assessment efficacy and safety of this herbal medicine on reducing LBP. Also, it is better to achieve superior outcomes, compare the effects of this herbal medicine with a placebo or standard medicine to be able to generalize results of study.

CONCLUSION

According to results of this study, *M. longifolia* could be applied for alleviating symptoms in patients with LBP.

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