

## EFFECT OF *ARCTIUM LAPPA* L. (BURDOCK) ROOT TEA ON CLINICAL SIGNS AND SYMPTOMS IN PATIENTS WITH KNEE OSTEOARTHRITIS

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**ABSTRACT:** *This study was designed to examine the effect of Burdock root tea on clinical signs and symptoms in patients with knee osteoarthritis (OA). Thirty-six patients (10 men and 26 women) aged 50-70 year-old with knee osteoarthritis referred to the physical medicine and rehabilitation department of the Tabriz University of Medical sciences Hospitals in 2013, were selected for the study and divided into two groups randomly. For all individuals along the 42 days of study period, the same drug treatments were considered. The intervention group received daily 3 cups of Burdock root tea (each cups contain 2gr/150 cc boiled water) half-hour after the meal. Control group received 3 cups contain 150 cc boiled water daily. The Knee Injury and Osteoarthritis Outcome Score (KOOS) Questionnaire, Timed Up and Go (TUG) and Visual Analog Scale (VAS) tests were used for clinical assessments. There was significant difference in pain intensity ( $P < 0.001$ ), scores of the KOOS Questionnaire ( $P = 0.020$ ) and TUG ( $P = 0.027$ ) between the two groups after treatment. Significant reduction in pain intensity ( $p < 0.001$ ), significant decrease in the mean score of TUG ( $P < 0.001$ ) and significant increase in the mean score of KOOS Questionnaire ( $P < 0.001$ ) was noted in Burdock root tea group.*

**KEYWORDS:** *Arctium Lappa* L., Clinical signs, Clinical trial, Knee Osteoarthritis.

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## INTRODUCTION

Osteoarthritis (OA) one of the most common rheumatic disorders is a progressive degenerative changes of joints that is more frequently present in the elderly (Brenner et al., 2003). Osteoarthritis, the leading cause of pain and disability, is estimated to affect approximately 15% of people in the Iran (Davatchi et al., 2008), and 15% of the world population (Egloff et al., 2012). The joint most commonly affected are the knee (Eftekhari-Sadat et al., 2013). It is known that Synovitis play an important role in the development of pain, joint inflammation and cartilage destruction and is directly responsible for several clinical symptoms (Brenner et al., 2003; Sellam and Berenbaum, 2010). Production of pro inflammatory cytokines and other inflammatory mediators in synovial fluid of joints have been shown in many studies (Brenner et al., 2003). Also these inflammatory mediators can be observed in systemic circulation of OA patients (Messier, 2008). It has been demonstrated that increased oxidative stress is a pivotal factor in pathogenesis of knee osteoarthritis (Suantawee et al., 2013). Overproduction of reactive oxygen species (ROS) that generated by neutrophils, macrophages and chondrocytes during acute inflammatory flares in OA, play a major role in promoting articular cartilage degeneration (Khan et al., 2008).

The treatment of OA includes the use of exercise, lifestyle modification, medication and joint replacement surgery (Conaghan et al., 2008). It is clear that drug therapies, surgery or joint replacement, have a lot of side-effects and are cost effective interventions. In recent years, the plants and their bioactive components has been more attention in prevention and treatment of chronic diseases (Eftekhari-Sadat

et al., 2013). One of beneficial plant is Burdock. *Arctium lappa* Linne, commonly known as Burdock, is a perennial herb in the family of *Asteraceae* (Kim et al., 2008). Burdock root has been used as a common vegetable for dietary use and an alternative medicine to treat various diseases in many countries for a long time (Predes et al., 2011; Lin, 1996). Burdock are rich in carotenoids, flavonoids, organic acids (caffeic acid and chlorogenic acid) (Azizov et al., 2012), and lignans ( lappool, arctin, diarectigenin, arctigenin) (Chan et al., 2011). It has wide range of biological activities, specifically anti-inflammatory and antioxidant activities (Predes et al., 2011; Lin, 1996).

Therefore, considering the high prevalence of OA and useful properties of Burdock root, and that until now there have been no human studies to investigate the effect of Burdock on clinical signs and symptoms in OA patients, we designed and performed the following study.

## MATERIAL & METHODS

### Burdock (*A. lappa*) root tea preparation

The Burdock (*A. lappa*) root tea was supplied in small tea bags. Each bag contained 2 g of annual root powder of *Arctium lappa* L. The Burdock (*A. lappa*) root tea bags were prepared by Iranian Institute of Medical Plants, (Karaj, Iran).

### Subjects and treatments

This was a randomized, parallel, 6- week intervention study with measurements at baseline and at the end of the intervention. The Ethics Committee of the Tabriz University of Medical Sciences approved this study. The sample size was determined based on the primary information obtained from the study by Khadem-Haghighian for IL-6. (Khadem-Haghighian, 2011). For an  $\alpha$  value equal to 0.05 and a power of 80%, the sample size was computed using this formula:  $N = (z_1^2 + z_2^2) * f(\alpha, \beta) / (\mu_2 - \mu_1)^2$ , ( $\alpha = 0.05$  and  $\beta = 0.2$ ) as 18 subjects per group, therefore thirty-six patients (10 men and 26 women) aged 50-70 year-old who had knee osteoarthritis (with disease severity from mild to moderate based on the criteria of American College of Rheumatology) referred to the physical medicine and rehabilitation department of the Tabriz University of Medical sciences Hospitals in 2013, were selected for study and divided in two groups randomly: Burdock root tea treated and control group. Subjects were excluded if they had the following: BMI > 40 kg/m<sup>2</sup> or BMI < 18.5 kg/m<sup>2</sup>, cardiovascular disease, diabetes mellitus, liver and kidney disease, any history of peptic or duodenal ulcers, smoking, alcohol intake, having an allergy to Burdock and use of non-steroidal anti-inflammatory drugs. We matched all participants in both groups on their drug therapy by considering the same drugs and same doses including 500 mg acetaminophen four times a day and 500 mg glucosamine one time a day for 6 weeks. The intervention group received daily 3 cups of Burdock root tea "each cups contain 2g/150 cc boiled water" (Barnes J, et al.,

2002) half-hour after the meal. Subjects were instructed to prepare their tea by brewing one tea bag per 150 cc boiled water for 10/min. Control group received 3 cups contain 150 cc boiled water daily for 6 weeks. Written informed consent was obtained from each subject and all subjects were asked to maintain their usual diet and physical activity throughout the study.

### Clinical examinations

The Knee Injury and Osteoarthritis Outcome Score (KOOS), Timed Up and Go (TUG) and the Visual Analog Scale (VAS) tests were used for clinical assessments.

The VAS is considered to be one of the best methods available for the estimation of the subjective characteristics or attitudes that cannot be directly measured. The VAS provides a continuous scale for magnitude estimation and consists of a straight line between two end-points (0 and 10). In the present study, we used VAS in order to measure the rate and intensity of the pain; so that 0 represents no pain and 10 represents the maximum tolerable pain. The patient marks on the line the point that they feel represents their perception of their current state (Gould, 2001).

The TUG is a simple test used to assess a person's mobility and fall risk. It measures the time that a person takes to rise from a standard armchair, walk 3 meters (about 10 feet), turn around, walk back to the chair and sit down. During the test, the person is expected to wear their regular footwear and use any mobility aids that they would normally require and walks at a comfortable and safe pace. The TUG is used frequently in the elderly population, as it is easy to administer and can generally be completed by older adults. One source suggests that scores of 10 sec or less indicate normal mobility, 11–20 sec are within normal limits for frail elderly and disabled patients, and > 20 sec means the person needs assistance outside and indicates further examination and intervention. A score of 14 sec or more suggests that the person may be prone to falls (Eftekharsadat et al., 2013).

The KOOS is a promising self-reported joint-specific measure which was developed to assess short and long-term patient-relevant outcomes following knee injury. It meets basic criteria of outcome measures and can be used to evaluate the course of knee injury and treatment outcome. The KOOS is a comprehensive instrument assessing five outcomes: pain, symptoms, activities of daily living (ADL), sport and recreation function, and knee-related quality of life. KOOS is patient-administered, the format is user-friendly and it takes about 10 min to fill out. The KOOS comprises five separately scored sub domains, based on 42 individual items: Pain (nine items); Symptoms (seven items); ADL Function (17 items); Sport and Recreation Function (five items); and Quality of Life (four items). Each item is scored from 0 (least severe) to 4 (most severe). For each sub domain as well as the total KOOS the score was normalized to a 0–100 scale with 100 being the best

possible outcome (Eftekhar-Sadat et al., 2013; Roos et al., 1998; Salavati et al., 2008).

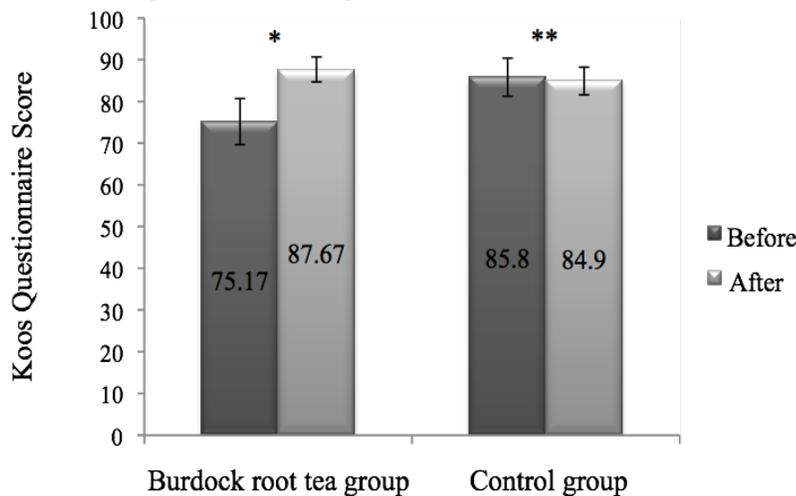
**TABLE 1. Med±IQR for VAS in Burdock root tea and Control groups.** All data are expressed as med ± interquartile range (IQR); VAS, Visual Analog Scale; \*Significant difference within groups throughout the study (P < 0.05); †Difference between groups in baseline and after intervention; \*\*Significant difference between groups after intervention.

Parameter	Measurement Period	Burdock Root Tea (N=18)	Control (N=18)	Z	p-Value†
VAS	Baseline	8±5	6±3.25	-1.585	0.113
	After intervention	5±5*	5.5±3	-4.041	<0.001**

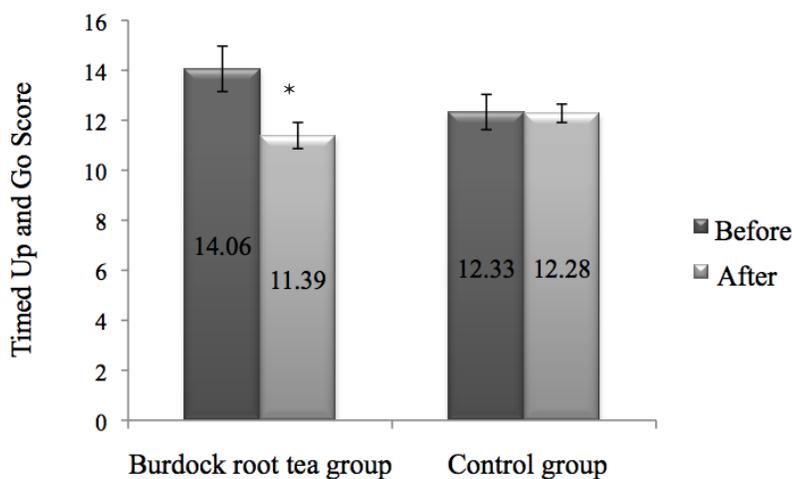
**Statistical analysis**

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSSInc, Chicago, IL, USA)

**FIGURE 1. Effect of Burdock root tea consumption on Knee Injury and Osteoarthritis Outcome Score (KOOS).** Error bars show standard deviation of the mean.\*p-value < 0.001; \*\*p-value = 0.747.



**FIGURE 2. Effect of Burdock root tea consumption on Timed Up and Go Score.** Error bars show standard deviation of the mean.\*p-value <0.001; \*\*p-value = 0.907.



version 16. The normality of the distribution of variables was determined by the Kolmogorov–Smirnov test. Ordinal variables were presented as median±interquartile range (MED± IQR), while quantitative variables were presented as mean±standard deviation of the mean (SD). Pretreatment and post-treatment differences in mean values were analyzed using paired t-test. Differences in baseline mean values between the two groups were analyzed using independent t-test. Analysis of covariance was used to identify any differences between the two groups after intervention, adjusting for baseline measurements and covariates. Differences in MED±IQR between the two groups were analyzed using Mann Whitney U-test. P < 0.05 was considered to indicate statistical significance.

**RESULTS**

Eighteen patients in the intervention group and 18 patients in the control group completed the study. In both groups, 27.8% of the subjects were men and 72.2% were women. Duration of disease in both intervention and control groups was 4.78 ±2.80 and 5.17±2.68 years, respectively. As presented in Table 1, there was significant difference in pain intensity between the two groups (P<0.001) after treatment. Significant reduction in pain intensity was noted in Burdock root tea group (p<0.001). Figure 1 presents the effect of Burdock root tea consumption on the KOOS Questionnaire. The mean score of KOOS Questionnaire in treatment group was significantly increased (P < 0.001) compared with baseline. Figure 2 presents the effect of Burdock root tea consumption on the TUG score. The mean score of the TUG in treatment group was significantly decreased (P < 0.001) compared with baseline. There was no significant difference in pretreatment scores of KOOS Questionnaire (P = 0.100), TUG (P=0.110) and pain intensity (P=0.113) between the two groups. There was significant difference in post-treatment scores of the KOOS Questionnaire (P=0.020) and TUG (P = 0.027) between the two groups.

**DISCUSSION**

This study is the first clinical trial that was conducted to assess the effect of Burdock root tea on clinical signs and symptoms in patients with knee OA. The results from this study showed that consumption of 6 g/d Burdock root for 42 days caused significant improvement in pain intensity and TUG score and significant increase in mean score of KOOS Questionnaire.

During the last decade, studies have suggested that

OA is an inflammatory disease. Pain, is the common symptom in OA. It is found that, interactions between inflammation and other characteristics of disease is the main reason of pain (Bonnet and Walsh, 2005). It is suggested that excess production of cytokines and growth factors from synovium, has an important role in OA even in the first stages. Excess production of these inflammatory mediators can induce synthesis of matrix degrading enzymes -that degrade the cartilage matrix- from synovium, cartilage and bone (Eftekharsadat et al., 2013; Bondeson et al., 2006), and can induce production of acute phase proteins such as C reactive protein (CRP) in the liver (Bruunsgaard, 2006). Levels of systemic high sensitivity C-reactive protein and inflammatory cytokines especially interleukin-6(IL-6), reflect synovial inflammation and are associated with level of pain and decreased function in OA patients (Berenbaum, 2013; Lee et al., 2013). In a study we demonstrated that consumption of 6gr burdock root tea for 42 day significantly decreased the levels of serum IL-6 and hs-CRP in patient with knee OA (Unpublished data). (Huang et al. 2010) showed that levels of the inflammatory cytokines, IL-6 and TNF- $\alpha$  were decreased after 7 day treatment with 100 mg/kg *Arctium lappa* L. (AL) powder orally, in mice with DSS-induced colitis, and indicated that AL has anti-inflammatory effects. (Zhao et al., 2009) demonstrated that Arctigenin, a bioactive constituent from *Arctium lappa* L. suppressed NO production and pro-inflammatory cytokines secretion, including TNF- $\alpha$  and IL-6 in a dose-dependent manner in LPS-stimulated macrophage. According to the role of inflammation in knee OA and considering positive effects of burdock root on inflammatory factors in previous studies, therefore we can suggest that burdock root tea consumption can improve clinical signs by decreasing inflammatory factors.

Oxidative stress is another important factor that has a substantial role in OA. (Altindag et al., 2007) indicated that oxidative stress is negatively correlated with collagen metabolism. Studies showed that inflammatory mediators stimulates the production of highly reactive oxygen species such as nitric oxide (NO) (Jayasuriya and Chen, 2013), Hydrogen peroxide and Superoxide in elderly chondrocytes. Superoxide anions have negative effects on collagen structure and lead to depolymerization of synovial fluid hyaluronate (Eftekharsadat et al., 2013). In our previous study we showed that consumption of 6gr Burdock root tea for 42 day significantly decreased the levels of serum MDA. While the levels of serum total antioxidants capacity (TAC) and activities of superoxide dismutase (SOD) were significantly increased (Unpublished data). (Lin et al., 2000) demonstrated Burdock's antioxidative effect on hepatocytes. They found that *A. lappa* could protect the liver cells by decrease the malondialdehyde (MDA) content in CCl<sub>4</sub> or acetaminophen-intoxicated mice. (Dong, 2008) reported that consumption of Burdock-tea caused increased SOD activity, reduced MDA content and enhanced glutathione peroxidase (GSH-Px) activity in mice. (Wang et al., 2006) showed that methanolic extracts of Burdock (MEB) and their

major components, Chlorogenic acid (CHA) and Caffeic acid (CA), showed inhibitory effect on LDL oxidation, increased activity of GSH reductase, GSH peroxidase, GSH transferase and catalase, and reducing effect on nitric oxide production of lipopolysaccharide (LPS)-induced RAW 264.7 cells. According to the beneficial effects of Burdock on oxidative status in previous studies, we therefore conclude that increasing antioxidant enzyme activity and improving body oxidative status is another possible mechanism by which burdock could improve clinical signs of OA. Our study had some limitations, including short study duration of 6 weeks, low sample size and no intervention studies on the efficacy of Burdock root in human. More clinical trials with higher larger sample population and a longer intervention period may be required in future.

## CONCLUSION

The results of the present study showed that consumption of Burdock root tea (6gr/day) for 42 days resulted in improved clinical signs and symptoms in patients with knee OA.

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