

# Effect of Capsaicin Cream on Chronic Low Back Pain in Patients With Inter-Vertebral Disc Herniation

Sedigheh Fayazi<sup>1</sup>; Mandana Farokhpyam<sup>2</sup>; Somaye Talali<sup>3,\*</sup>

<sup>1</sup>Chronic Disease Care Research Center, Department of Nursing, Nursing and Midwifery School, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, IR Iran

<sup>2</sup>Department of Pharmacy School, International Branch of Shahid Beheshti University of Medical Sciences, Tehran, IR Iran

<sup>3</sup>Research Center of Herbal Medicine, Department of Nursing, Nursing and Midwifery School, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, IR Iran

\*Corresponding author: Somaye Talali, Research Center of Herbal Medicine, Department of Nursing, Nursing and Midwifery School, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, IR Iran. Tel: +98-9126587651, E-mail: somayetalali@yahoo.com

Received: March 3, 2015; Accepted: April 27, 2015

**Background:** Low back pain is one of the most common debilitating disorders worldwide and the third cause of visiting a physician. One of the most common causes of low back pain is spinal disc herniation. Still there is no general agreement on the most effective treatment for it.

**Objectives:** This study aimed to determine the effect of Capsaicin cream on low back pain in patients with inter-vertebral disc herniation in Ahvaz.

**Patients and Methods:** This was a double blind clinical trial in which 43 patients with chronic low back pain, according to characteristics of the subjects, were randomly divided into two groups of treatment (n = 23) and control (n = 20). Data collection instruments included demographic specifications and visual analogue scale (VAS) questionnaire completed on arrival and at the first, second and third weeks after intervention. The treatment and placebo groups used the ointment for three weeks and three times a day as a thin layer on the painful position. Data entered SPSS (version 18) and analyzed using the analytical descriptive statistics.

**Results:** There was a significant difference in the average pain intensity between the groups of study pre-and post-intervention ( $P = 0.0001$ ) and the rate of using analgesics in the treatment group significantly decreased ( $P = 0.008$ ). Also patients' satisfaction was significantly different between the two groups using the ointment ( $P = 0.0001$ ).

**Conclusions:** Capsaicin cream has beneficial effects on pain relieving and reducing analgesic use in patients with inter-vertebral disc herniation. Therefore, the ointment can be recommended in the treatment of low back pain caused by inter-vertebral disc herniation.

**Keywords:** Vertebral; Low Back Pain; Capsaicin

## 1. Background

Low back pain is one of the most common health problems in America and other countries of the world and is the most common cause of disability and absence from work (1-3). Lower back pain has many causes. Inter-vertebral disc herniation is one of the common causes of disease, especially in the third and fourth decades of life (4) and a major cause of function limitation and impairment of quality of life and chronic disability in both sexes (5). Prevalence of disc herniation is more common in men than women (6). Its prevalence is 7 - 37% in different countries and 8.20% in Iran, but there is no exact statistics regarding its prevalence rate in total (7). Inter-vertebral disc acts as a joint between the vertebrae and the shock-absorbing, in severe and sudden pressure on the spine, fibrous fibers of the outer layer of inter-vertebral disc would be torn and the central gelatinous disc substance would be herniated outward called inter-vertebral disc herniation (8). The destructive cause of lumbar disc is complex and not fully explained, so that its cause would be considered as a multifactorial disorder including a

number of genetic and environmental factors and their interactions (9). The most common clinical display of the disease is low back pain and the phenomenon is because of segmental annulus innervation in lumbar disc, which is the most sensitive anatomically structure to pain (10, 11). Pain affects these patients' health, performance and quality of life; chronic pains would cause physical and mental health involvement in adults and children (12). Daniel et al. stated that many patients with chronic pain have personality disorders, drug dependency, instability in family relationships and career incompatible (13). Many different treatment methods have been used to treat low back pain in patients with inter-vertebral disc herniation. Available treatments include proper training, physical activity without doing heavy work, medical treatments including non-steroidal anti-inflammatory drugs, physiotherapy, use of medical belts, acupuncture and herbal medicines (14, 15). The use of herbal medicines is apart of holistic medicine and its application along with modern medicine is effective in improving these

patients (16). Infact, many complementary medicine majors such as acupuncture and herbal therapy are under the banner of natural medicine (17). In the recent years, herbal therapy has been more considered as one of the complementary medicine aspects (18). The use of medicinal plants in Egypt, Indian, China and Iran dates back more than other countries (19).

So far, many natural materials such as capsaicin have been used in traditional medicine to relieve low back pain. Capsaicin contains substances like Capsanthin, hence expected to have mutual effects of topical irritant (20). In a study, therapeutic effects of Capsanthin were shown in diabetic neuropathy, osteoarthritis and herpetic neuralgia (21). The use of these materials is because of such effects in combinations of these natural elements (20). Long-term and frequent use of capsaicin cream desensitizes secreting fibers of substance P and reduces the substance secretion, thus relieving pain (22, 23). This material has analgesic effect in cases such as muscular low back pains, pains arising from osteoarthritis, cluster headaches, lower urinary tract allergies and a variety of neuralgia (24). Weiser's study showed that the ointment is helpful in the treatment of patients with chronic pain of soft tissue and is also effective in patients with chronic low back pain (25). The results of study conducted by Moghaddamnia showed that Capsaicin cream is only effective on pain at rest in osteoarthritis and has no effect on moving pain and arthritis; also it does not have any priority compared to Diclofenac gel and placebo ointment (26).

Despite the dramatic increase in clinical trial conducted in the past decade, only 2% of trials examined the issue of low back pain (27). Some studies have been performed on the effect of ointment made from the plant's on peripheral pain including diabetic neuropathy, osteoarthritis, pain after surgery, chronic low back pain with unknown origin and soft tissue pain, but there is no study about the use of complementary medicine methods including capsaicin cream in relieving pain in patients with low back pain caused by inter-vertebral disc herniation, in which pain originates from the central nervous system and stimulates recipients of pain in this area.

## 2. Objectives

No similar studies were found in Iran, so this investigation was performed to help improving the quality of care provided to patients and enhancing the quality of life and increasing their life satisfaction by decreasing patients' pain. According to the World Health tendency to use complementary medicine, especially medicinal herbs, the use of capsaicin cream was assessed in relieving chronic low back pain because of inter-vertebral disc herniation to improve patients' quality of life.

## 3. Patients and Methods

This study was a random double-blind clinical trial with placebo-controlled performed on all patients with

chronic low back pain caused by inter-vertebral disc herniation in Ahvaz. An approval was obtained from relevant authorities and patients. First, according to the research sample properties and inclusion and exclusion criteria, the number of research samples was determined as 40 patients. Based on pilot research and possibility of loss, 43 persons were randomly allocated into two groups. In the first group ( $n = 23$ ), capsaicin cream and the second group (20 patients), ointments containing non-drug and ineffective material were used as non-drug control. Inclusion criteria were having low back pain for at least three months and chronic inter-vertebral disc herniation diagnosis of L5 and S1 by an expert, BMI less than 30, no pregnancy and lactation and not having skin diseases, obtaining a score higher than 5 based on the VAS criterion, no addiction and a history of surgery. Exclusion criteria were not willing to continue the intervention, mental illness and the need for surgery in the lumbar region.

Patients entered the study after diagnosis by a physician and completing a written consent form. The way of doing research, its terms and goals and the probability of being in one of the groups (treatment or placebo) were explained to all the participants. Drugs used in this study, capsaicin cream with 0.5% (Goldaru Co. Iran) and placebo ointment containing petrolatum and glycerin similar to pepper ointment for color, odor and concentrations but without effective substance, were prepared and coded by the research assistant in similar containers. Data collection instrument included demographic information and patient information and VAS questionnaire. VAS consists of 11 levels of pain intensity from zero as no pain to 10 as the most feeling of pain. This questionnaire is a standardized scale to assess pain and its validity has been confirmed in several studies (28). In the first session, for both groups of patients, demographic information and patient information form completed by the researcher and using the patient records information in the office. Patients were trained about how to express pain intensity by VAS ruler and completed for each patient by the researcher.

Then the patients were instructed to put the ointment on painful position as a thin layer three times a day for three weeks. Patients were also explained that the drug may have adverse effects such as mild skin irritation, hot and itchy feeling and these adverse effects would be usually decreased or disappeared after frequent use, during the treatment period; patients were followed up by phone contacts. At the end of the first, second and third weeks post-treatment, the pain intensity was measured to evaluate treatment efficacy. And at the last session, the VAS questionnaire and the use of analgesics was recompleted for patients and satisfaction form was given to them to declare their satisfaction with the ointment. Finally the information obtained was analyzed using SPSS-18 software and descriptive statistics (frequency, percentage, mean, standard deviation) and inferential statistics (variance analysis, chi-square and paired t-test) ( $P < 0.005$ ).

The ethics committee of Ahvaz Jundishapur University of Medical Sciences approved the study (ETH-303). Formal authorization was obtained from Disease Research Centre of Ahvaz Jundishapur University of Medical Sciences and Mahshahr oil hospital. Both the purpose and method of research were described for participants and informed consent to participate in the study was received from all of them.

#### 4. Results

Two patients in capsaicin group were excluded from the study because of unwillingness and finally 43 patients completed the study. Participants' information are presented in Table 1. Data analysis showed no statistically significant difference between the two groups for demographic properties.

Information about the patients' disease is presented in Table 2. There was no statistically significant difference. Table 3 depicts patients' information for their pain intensity mean at the beginning of intervention and the end of the first, second and third weeks of intervention. Pain intensity mean in the beginning of intervention in the two groups did not have a statistically significant difference ( $P = 0.793$ ). Also the pain intensity means at the end of the first and second weeks of intervention between the two groups showed no statistically significant difference, respectively ( $P = 0.583$ ) and ( $P = 0.73$ ); however, there was a meaningful difference between the pain intensity mean at the end of third week of intervention and before the intervention by t-test ( $P = 0.008$ ). Comparing the rate of analgesics use in beginning of intervention did not show a significant difference ( $P = 0.677$ ), while comparing the rate of analgesics use after the interventions showed statistically significant difference ( $P = 0.007$ ). Also examining patients' satisfaction with the ointment use showed a significant dif-

ference between the two groups ( $P = 0.0001$ ). For adverse effects, three patients in the case group and one patient in the placebo group experienced mild redness and itching in the position they used the ointment.

**Table 1.** Distribution of Patients With Chronic Low Back Pain Due to Inter-Vertebral Disc Herniation Based on Demographic Specifications

| Placebo Group          | Pepper Group | Demographic Profiles |
|------------------------|--------------|----------------------|
| Age, y                 | 44.1 ± 11.07 | 42.45 ± 11.07        |
| <b>Gender</b>          |              |                      |
| Male                   | 10           | 7                    |
| Female                 | 13           | 13                   |
| <b>Marital status</b>  |              |                      |
| Married                | 18           | 17                   |
| Single                 | 5            | 3                    |
| <b>Nationality</b>     |              |                      |
| Arab                   | 10           | 9                    |
| Persian                | 8            | 5                    |
| Other                  | 5            | 6                    |
| <b>Education</b>       |              |                      |
| Illiterate             | 10           | 6                    |
| Lower diploma          | 9            | 8                    |
| Diploma and higher     | 4            | 6                    |
| <b>Occupation</b>      |              |                      |
| Housewife              | 11           | 7                    |
| Clerk                  | 5            | 5                    |
| Hard jobs              | 7            | 8                    |
| BMI, kg/m <sup>2</sup> | 25.55 ± 1.35 | 25.04 ± 1.37         |

**Table 2.** Average of Patients With chronic Low Back Pain Due to Intervertebral Disc Herniation Based on Duration and Kind of Drugs Used in Two Groups

| Patient information               | Pepper Group | Placebo Group | P Value |
|-----------------------------------|--------------|---------------|---------|
| Disease duration, y               | 7.7 ± 4.82   | 7.15 ± 5.01   | 0.72    |
| <b>Type of analgesic</b>          |              |               |         |
| Ibuprofen                         | 11           | 12.60         |         |
| Diclofenac                        | 7            | 5             |         |
| Other medications                 | 5            | 3             |         |
| <b>Ointment side Satisfaction</b> |              |               |         |
| Have                              | 3            | 1             | 0.292   |
| Not have                          | 20           | 19            |         |
| <b>Hospitalization history</b>    |              |               |         |
| Have                              | 8            | 6             | 0.5     |
| Not have                          | 15           | 14            | 0.50    |

**Table 3.** Average of Pain Intensity Based on the VAS Scale in the Two Groups of Pepper and Placebo before and after intervention

| Pain intensity | Pepper Group | Placebo Group | P Value |
|----------------|--------------|---------------|---------|
| On arrival     | 7.25 ± 1.25  | 7.35 ± 1.13   | 0.793   |
| First week     | 7.05 ± 1.14  | 7.25 ± 1.11   | 0.580   |
| Second week    | 6.65 ± 1.08  | 7.20 ± 0.96   | 0.073   |
| Third week     | 5.95 ± 1.05  | 7.05 ± 1.39   | 0.008   |

## 5. Discussion

Low back pain is one of the most common complaints related to muscular-skeletal system. Many therapeutic approaches have been used to treat low back pain.

Despite access to conventional treatments, patients with chronic low back pains tend to use complementary and alternative medicine to relieve their symptoms (29). One of the treatment methods is use of complementary and alternative therapies such as medicinal herbs. The reason of using natural materials in relieving pain may be because these materials have fewer side effects due to the origin of preparation and less tissue damage than chemicals. In traditional medicine, the medicinal herbs were largely used among which the capsaicin has been widely applied (30).

In addition, to reduce systemic adverse effects of oral or parenteral drugs, the use of topical preparations has been more common in the treatment of chronic diseases such as chronic low back pain, which may require long-term treatment and the study aimed to apply capsaicin cream on 43 patients with chronic low back pain in the two groups of pepper [23] and placebo groups [20] treated three times a day for three weeks. The findings showed a statistically significant difference between pain intensity of patients in both groups at the beginning and end of the intervention ( $P = 0.0001$ ). Chrubasik et al. showed that capsaicin cream generally improves pain in patients with chronic pain of soft tissue (25). Frerick et al. (31) showed that the use of capsaicin cream significantly reduced pain in patients with nonspecific chronic low back pain. Moghaddamnia et al. (26) showed that the use of capsaicin cream has not been effective for pain relief in patients moving with osteoarthritis and had no superiority over placebo ointment and Diclofenac gel in relieving pain at rest. This could be because of differences in the origin of pain and the disease stages. Comparison of pain intensity in the first, second and third weeks of intervention between the two groups showed that in the first and second weeks no relief effects were observed, and only at the end of intervention the ointment was more effective. While in Chrubasik study, during the first and second weeks of intervention, therapeutic effects of capsaicin cream were found (25), which is inconsistent with the present study and this could be because of differences in the origin of pain and disease type or a greater number of studied samples. Comparing the mean of us-

ing analgesics, there was a statistically significant difference in the two groups. In Kim et al. study performed on pain after inguinal hernia surgery in children, using the ointment reduced topical analgesics requirement to 31% (32), which is consistent with the present study. No statistically significant difference was observed between the two groups comparing unwanted adverse effects resulting from using the ointment such as itching, burning feeling and light red in the two studied groups after the intervention. In Frerick et al. study and Keitel study, adverse effects were seen in patients in the placebo and treatment groups, which is consistent with the results of this study (31, 33). Also comparing patients' satisfaction of the two groups with performing the treatment group, they expressed their satisfaction using the ointment. In Chrunbasik et al. study, patients and researchers stated their satisfaction using the ointment and its safety (25), which is consistent with these results.

Use of capsaicin cream is a simple method without adverse effects for pain relief in patients with chronic low back pain caused by inter-vertebral disc herniation. However, it seems to achieve better results in case of longer duration of intervention.

### 5.1. Research Limitations

Pain is a subjective phenomenon and psychological, social and cultural factors affect it and controlling factors is out of the researcher's hands. Also responses given by the research units are considered correct and acceptable and there is no instrument to assess their verification.

## Acknowledgements

This paper was extracted from the thesis of Somaye Talali financially supported by a grant (Irct: MPRCO23) from Vice-Chancellor for flora medicine Centre of Ahvaz Jundishapur University of Medical Sciences. We thank Mahshahr oil hospital and all those who helped in this research.

## Financial Disclosure

Ahvaz Jundishapur University of Medical Sciences.

## Funding/Support

Ahvaz Jundishapur University of Medical Sciences.

## References

- Hoy D, Bain C, Williams G, March L, Brooks P, Blyth F, et al. A systematic review of the global prevalence of low back pain. *Arthritis Rheum.* 2012;**64**(6):2028-37.
- Medline Plus U.S. National Library of Medicine.. *Low-Back Pain-Chronic.* Available from: <http://www.nlm.nih.gov/medlineplus/ency/article/007422.htm>.
- National Institute of Neurological Disorders and Stroke.. *Low-Back Pain Fact Sheet.*: NIH; Available from: [http://www.ninds.nih.gov/disorders/backpain/detail\\_backpain.htm](http://www.ninds.nih.gov/disorders/backpain/detail_backpain.htm).
- Williams KD, Park AL. Lower back pain and disorders of intervertebral discs. In: Canale ST editor. *Campbell's Operative Orthopaedics.* Philadelphia: Mosby; 2003. pp. 1955-2050.
- Waddell G, Burton K. Information and advice for patients. *The back pain revolution.* Ediburg: Hurchill Livingstone. pp. 323-42.
- Jabbari M, Mani Kashani K. [Study of Frequency of Low Back Pain and Lumbar Disc Herniation in Patients of Hamadan MRI Center in 2002]. *J Hamadan Univ Med Sci.* 2006;**2**(32):35-7.
- Ghafary M. [Incidence and recurrence of disabling low back pain and neck pain in the Industrial Community Forums]. *Fasl Name Health work Iran.* 2007;**2**(4):36-40.
- Speed C. Low back pain. *BMJ.* 2004;**328**(7448):1119-21.
- Omair A, Holden M, Lie BA, Reikeras O, Brox JI. Treatment outcome of chronic low back pain and radiographic lumbar disc degeneration are associated with inflammatory and matrix-degrading gene variants: a prospective genetic association study. *BMC Musculoskelet Disord.* 2013;**14**:105.
- Allon AA, Schneider RA, Lotz JC. Co-culture of Adult Mesenchymal Stem Cells and Nucleus Pulposus Cells in Bilaminar Pellets for Intervertebral Disc Regeneration. *SAS J.* 2009;**3**(2):41-9.
- Rengachary SS, Balabhadra RSV. Black disc disease: a commentary. *Neurosurg Focus.* 2002;**13**(2):1-4.
- Fitzcharles MA, DaCosta D, Ware MA, Shir Y. Patient barriers to pain management may contribute to poor pain control in rheumatoid arthritis. *J Pain.* 2009;**10**(3):300-5.
- Daniel MS, Long C, Hutcherson WL, Hunter S. Psychological factors and outcome of electrode implantation for chronic pain. *Neurosurgery.* 1985;**17**(5):773-7.
- Liddle SD, Baxter GD, Gracey JH. Treatment of chronic low back pain. *Pain.* 2005;**110**(1-2):176-90.
- Kinkade S. Evaluation and treatment of acute low back pain. *Am Fam Physician.* 2007;**75**(8):1181-8.
- Chou R, Huffman LH, American Pain S, American College of P. Medications for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. *Ann Intern Med.* 2007;**147**(7):505-14.
- Cooke B, Ernst E. Aromatherapy: a systematic review. *Br J Gen Pract.* 2000;**50**(455):493-6.
- Buckle J. Aromatherapy: What is it? . *Herbal Gram.* 2003;**57**:50-6.
- Zargari A. *Medicinal Herbs.* Tehran: Tehran university; 1992.
- Lynn B, Ye W, Cotsell B. The actions of capsaicin applied topically to the skin of the rat on C-fibre afferents, antidromic vasodilatation and substance P levels. *Br J Pharmacol.* 1992;**107**(2):400-6.
- American college of rheumatology subcommittee on osteoarthritis.. Recommendation for medical management of osteoarthritis of the hip and knee. *Arthritis Rheum.* 200;**48**:1905-15.
- Caterina MJ, Julius D. The vanilloid receptor: a molecular gateway to the pain pathway. *Annu Rev Neurosci.* 2001;**24**:487-517.
- Rains C, Bryson HM. Topical capsaicin. A review of its pharmacological properties and therapeutic potential in post-herpetic neuralgia, diabetic neuropathy and osteoarthritis. *Drugs Aging.* 1995;**7**(4):317-28.
- Avicenna.. [Law in Medicine] translated by Sharafkandi, Tehran: Soroush publisher; 1983.
- Chrubasik S, Weiser T, Beime B. Effectiveness and safety of topical capsaicin cream in the treatment of chronic soft tissue pain. *Phytother Res.* 2010;**24**(12):1877-85.
- Moghaddamnia A. Comparison The effects of red pepper jell ointment and diclofenac topical gel in therapeutic of single joint osteoarthritis. *Babol Scie Med J.* 2003;**3**(19):12-7.
- Nachemson A, Waddell G, Norlund AI. *Chronic low back pain. Neck and Back Pain: The scientific evidence of causes, diagnosis, and Treatment.* Philadelphia: Lippincott Williams & Wilkins; 2000.
- Gallagher EJ, Bijur PE, Latimer C, Silver W. Reliability and validity of a visual analog scale for acute abdominal pain in the ED. *Am J Emerg Med.* 2002;**20**(4):287-90.
- Hughes CM, Quinn F, Baxter GD. Complementary and alternative medicine: perception and use by physiotherapists in the management of low back pain. *Complement Ther Med.* 2011;**19**(3):149-54.
- Sheikh Al ryys Abo Ali sin.. [Law in medicine, second books] Translated by Sharafkandi,, 1th ed Tehran: Soroush Publisher; 1983.
- Frerick H, Keitel W, Kuhn U, Schmidt S, Bredehorst A, Kuhlmann M. Topical treatment of chronic low back pain with a capsicum plaster. *Pain.* 2003;**106**(1-2):59-64.
- Kim KS, Kim DW, Yu YK. The effect of capsicum plaster in pain after inguinal hernia repair in children. *Paediatr Anaesth.* 2006;**16**(10):1036-41.
- Keitel W, Frerick H, Kuhn U, Schmidt U, Kuhlmann M, Bredehorst A. Capsicum pain plaster in chronic non-specific low back pain. *Arzneimittelforschung.* 2001;**51**(11):896-903.