Low back pain – complex approach of treatment CAM modalities (acupuncture and other type of dry-needling, "Targeted RF non invasive physiotherapy" for low back pain)

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Low back pain – complex approach of treatment by different CAM modalities (acupuncture and other type of dry-needing. "Targeted RF non invasive physiotherapy" for low back pain)

Absract

For at least 2,500 years, acupuncture has been an integral part of traditional Chinese Medicine. Recently more people have been diagnosed with chronic disease and many of them have been poorly treated with conventional therapies. Those patients frequently prefer other forms of complementary medical treatments. Based on the theory of homeostatic equilibrium being the basis of health, acupuncture focuses on restoring the homeostasis by manipulating the complementary and opposing elements of yin and yang. It is possible that by affecting afferent nerve signaling, acupuncture may influence the release of endogenous opioids to promote pain relief. Our objective is to give western trained physicians clinical applications together with acupuncture and modern physiotherapeutic - equipment (Booster) to accommodate accelerating interests in acupuncture and related techniques in modern complex treatment of chronic low back pain. In recent prospective Phase I/II study statistical data have verified the relevant end-points of the study: the safety, the quality of life (QoL), the rest time, duration of painless state, and the cost/benefit ratio.

Introduction

Thirty-five RCTs covering 2861 patients were included in a systematic review [1]. There was insufficient evidence to make any recommendations about acupuncture or dry needling for acute low back pain, but for chronic low back pain, results showed that acupuncture is more effective for pain relief than any treatment or sham treatment, in measurements taken up to three months. The results also showed that for chronic low-back pain, acupuncture is more effective for improving function than any other treatment, in the short term. [2] Acupuncture is not more effective than other conventional and "alternative" treatments. When different types of acupuncture were added to other conventional therapies, they relieved pain and improved function better than the conventional therapies alone with less intake of pharmacologic substances and had fewer side effects. In our randomized pilot study we were going to apply more complementary and alternative methods (CAM) and treatments for low back pain and evaluated their effect on visual analogue scale (VAS), & Quality of life (QoL) of patients [3]. CAM modalities including —dry needlingl, the lately improved non- invasive RF therapy appear to be a useful adjunct to other therapies for chronic low-back pain with individually developed life-style management. (Personalized medicinel).

Although chronic low-back pain is usually a self-limiting and benign disease that tends to improve spontaneously over time, a large variety of therapeutic interventions are available for its treatment. Recovery time is different at each patient depending on his/her additional physical condition. Most patients are older due to developed degenerative soft-tissue damage which is a growing problem all over the world that should be treated [4].

Definitions for low back pains

Lumbar strain (acute/chronic) is a stretch injury to the ligaments, tendons, and/or muscles of the low back. The stretching incident results in microscopic tears of varying degrees in these tissues. Lumbar strain is considered one of the most common causes of low back pain. The injury can occur because of overuse, improper use, or trauma. Soft-tissue injury is commonly classified as "acute" if it has been present for days or for weeks. If the strain lasts longer than three months, it is referred to as "chronic." Lumbar strain most often occurs in people in their 40s, but it can happen at any age. The condition is characterized by localized discomfort in the low back area with onset after an event that mechanically stressed the lumbar tissues. The severity of the injury ranges from mild to severe, depending on the degree of strain and resulting spasm of the muscles of the low back.

What are common causes of lower back pain?

- protruding, herniated, or ruptured disc (operation is questioned)
- cauda equina syndrome (needs to be operated urgently)

- Sciatica is a condition in which a herniated or ruptured disc presses on the sciatic nerve, the large nerve that extends down the spinal column to its exit point in the pelvis and carries nerve fibers to the leg
- Spinal degeneration
- Spinal stenosis
- Osteoporosis
- Skeletal irregularities
- Fibromyalgia
- Spondylitis

According to recommendations of international guidelines in the modern diagnosis and treatment of low back pain there are more modalities that can be individually decided. Regarding diagnosis, it is very important to differentiate between - specific and - aspecific or -nonspecific low back pain. The term "specific low back pain" includes all diseases and pathologies with well-defined aetiology and pathological process, including bacterial spondylitis, rheumatic spondylarthropathies, primary or secondary tumours, malignancies, myelon- or cauda equine compression, paresis, metabolic base diseases, pathological or nonpathological fractures which are suspected. The presence of the so-called - red flags indicate - specific low back pain. This type of low back pain requires quick and precise diagnosis and specific treatment. All other kinds of low back pain, even those with very painful radiculopathy, and without paresis, cauda- or myelon compression can be considered as aspecific low back pain, there is no need for any diagnostic imaging methods, because they would not influence the treatment. Investigation and flow-chart of assessment have a rigorous algorithm: (see Figure 1.)

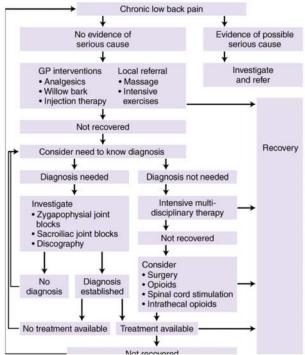


Figure 1. Flowchart of management for low back pain

Patient assessment should involve the following as a basic guideline for low back pain management:

- Algorythm for diagnose and treatment
- Identify low back diseases that place the patient at risk for pain
- Differentiate between chronic and acute pain and their treatment.
- Identify pain assessment tools used
- The basic neurophysiologic pain response
- Pharmacological and non-pharmacological approaches to pain management
- Differentiate between addiction, tolerance and dependence

- Discuss commonly performed nerve blocks and associated nursing implications
- Apply pain management instruments to practice situations
- The management of pain in the patient with cancer (recognized)

The course consists of diagnostic triage, Case history, Physical examination: Lasegue test and spinal palpation and motion tests, Imaging (not the first step), Electromyography and Prognostic factors. The main question is which of the following therapies is the best for the patient.

Our methodolical considerations

In our recent trial we have turned to acupuncture (with the application of a unique technic) and another noninvasive method. Our objective is to choose the effective acupuncture points and techniques, [4], [5]. We sort low back pain to the WEI Syndromes in TCM (in western terms: Polyneuritis, polyneuropathy, acute, chronic myelitis, periodical paralysis, hysteric paralysis, paresis)

WEI syndromes are characterized with following symptoms

- Cause: pathogenous Heat hurts the Lung, Yin fluid does not spread, nourish surface, tendons or muscles.
- Spleen-Stomach, Heat in Yang-Ming function-circle
- Additionally: Kidney Essence, Liver Blood Deficiency
- Weakness of muscles improved gradually...
- Excessive Heat in Lung, Stomach (acupoints for use [6] : Lu 5, UB 13, ST 44)
- Dampness-Heat Retencion (acupoints for use : UB 20, Sp 9)
- Yin Deficiency in Liver, Kidney (acupoints for use: UB 18, UB 23, KI 3)+ Huatuojiaji

Acupoints: St 31, St 34, St 36, GB 34, GB 30, GB 39, St 41

Damage and inhibited Qi and blood

Pathogenous Dampness – Cold in Kidney Channel have causes: (For pattern "Kidney Qi Deficiency": "Warming which is Cold, diminishes Dampness and Weat" (Huang Di Neiting, "The Yellow Emperor")

- Kidney Yin-Yang Xue (long-term diseases, sexual abuses, etc.)
- Stagnation of Qi and Blood
- Lumbar region: this is the "Palast of Kidney residence Kidney-UB : both of them attacked
- Other importance: Du Mai Channel (Stability, Permanence, —standing ability in mental too)

Dampness and cold in kidney

- Rapid start, lumbar rigidity, pain, weakness
- Warming collaterals, warming Cold, dissolving Dampness, (UB-TaiYang)
- Acupoints: UB 23, DU 3, UB 26, UB 32, UB 40
- DU3+ UB 26+UB32: regulation of Kidney Qi, activating Yang Qi, DU Mai

Kidney deficiency (Yin and Yang)

Longer time persisting pain, leading to legs, cold extremities, tiredness, weak knees

• Basic aim is : strenghten Kidney Qi-, mainly with DuMAi , UB, Kidney points

Acupoints: UB 23, DU4, UB 52, KI3, UB 40, Warming and strengthening Kidney Deficiency: UB52+DU4+ KI3

Pain due to traumatic injury

- Basic: helping the better blood circulation, block- removing from channels and collaterals,
- pain-killing UB-TaiYang and Ahshi points
- Acupoints : Ahshi: "where is painl, UB 17, UB32, UB 40, SI3
- In case of "Strong pain": Du26

In literature, each of the acupuncture (dry needling) modalities (true, sham, and placebo) associated with conventional treatment achieved clinical improvement after 3 weeks which was greater than that achieved

by conventional treatment alone in patients with acute/chronic low back pain, although there were no significant differences among the different forms of stimulus. [7] Which techniques should be chosen among the CAM facilities listed bellow?

- Acupuncture (permanent technique / short time needling), trigger point AP, e.t.
- Acupuncture microsystem (Ear [8], ECIWO, Scalp-Chinese, YNSA-Japanese)
- IMS (intramuscular stimulation)
- Neuraltherapy—(according to Hunecke, Germany: small dosage of analgetics)
- MESOTHERAPY-Guna (inj. "Lumbar", "Ischias", "Matrix"), Milano Univ. Italy
- Moving-massage therapy (Manual Medicine, Tuina, Qi-gong)
- Electrotherapy, TENS
- Additional "Targeted RF Stimulation with "-Booster [9]

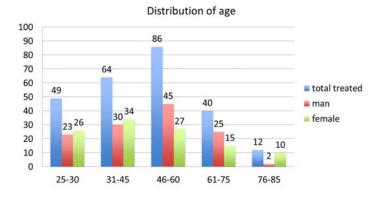
Our target was to assess the effects of acupuncture and other CAM therapies for the treatment of non specific low back pain and dry-needling combined with targeted RF stimulation (Booster) for myofascial, musculoscleteal pain syndrome in the low-back region with randomized controlled trial. [10], [11]. Intradiscal Radiofrequency Thermocoagulation (IRFT) and Intradiscal Electrothermal Therapy (IDET) are known as invasive forms of thermotherapy. Radiofrequency (RF) lesions not only target the rami dorsales to relieve facet pain, but also aim to reduce the nociceptive input from painful intervertebral discs. [12]. Percutaneous Intradiscal Radiofrequency Thermocoagulation (IRFT) has been used for this purpose. In this procedure a RF cannula is placed in the center of the disc and a lesion is then made here. Intradiscal electrothermal therapy (IDETTM) consists of heating the outer annulus of the intervertebral disc. A flexible intradiscal catheter with a temperature controlled thermal resistive coil is passed through a trocar into the annulus of the disc and is heated to a temperature of 70 degrees centigrade. This procedure has been developed as an alternative treatment to spinal fusion for patients with unremitting pain hypothesized to be caused by internal disc disruption (IDD).

Our aim was to introduce additive and non-invasive heat therapy for chronic low back pain. The purpose of the "Booster" equipment is to increase the blood flow in the treatment area. Selection at cellular level does not occur, only a heating of the deep layers of tissue in the region where the electrode is positioned superficially. (not invasive). The deep-heating effect is a result of Joule-loss and leads to vascular dilatation in the treatment area, that, in turn, improves blood perfusion and thus the drugs (and more oxygen) are transported to the treatment area. The temperature in this area is 37-39°C (moderate, so-called classic "Hyperthermia"), and this is the optimum temperature for the Booster's effect. The Booster must be adjusted to the pharmacokinetic parameters of the drugs used to achieve the maximum effect. The deep moderated "Hyperthermia" activates the microcirculation to and into the capillaries (capillary filtration capillary pressure etc.), increases micro-vascular perfusion, the local oxygen content in the tissue, and the nutrients and phagocytes in the treatment area. The increased temperature also regulates the cell cycle by changing the calcium ion binding. In addition, the following effects in the blood and tissue can also be achieved [13]:

- Increased fibroblast activity and increased capillary growth
- Increased nutrient concentration and metabolic activity
- Synergetic increase in the field-dependent effects (optimization of membrane stimulation and
- Activation of signal channels
- Increased reactions to heat and field exposure (mainly the development of Heat Shock Proteins, HSP 70)
- Increased venous and lymphatic flow
- Changes in the physical properties of the tissue

Recruitment commenced between 2011-2012, after 499 patients had been enrolled (249 to receive acupuncture + Booster treatment and 250 for control). 249 consecutive patients admitted to the rehabilitation unit were included in the study after informed consent. Other 250 patients received conventional pain killer pills and physiotherapy (Galvanic, Ultra sound treatment, and Infrared Soft Laser. Inclusion criteria were the following: 1) Diagnostic triage, 2) Case history, 3) Physical examination: Lasegue test and spinal palpation and motion tests, 4) Imaging, CT, MRI 5) B) Prognostic factors, age: 25-85, excluding criteria: ruptured disc, Caudal-syndrome which needs urgent operation. All patients gave

informed consent to participate in the study, which was performed according to the guidelines of the local ethics committee. The participants were not informed of the possibility of being assigned to either the acupuncture or to the no-acupuncture group. Ethics Committee approval was granted and the trial was performed in accordance with the Declaration of Helsinki. All the recruited patients went under rheumatic rehabilitation program using the Hungarian standard rehabilitation protocol. 249 of the patients received additional acupuncture therapy using the permanent dry needling method plus loco-regional heat therapy, and these patients were regarded as the "Acupuncture-Booster" group.



Treated Patients N=249

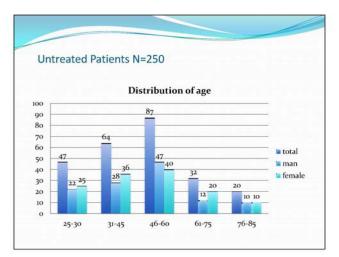
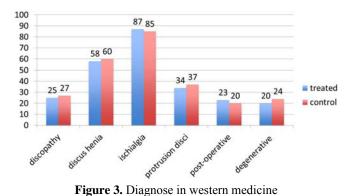


Figure 2. Distribution of patient (gender, age) treated and untreated



Diagnose

Procedure

A prospective, assessor-blinded randomized controlled trial was carried out in an outpatient rehabilitation unit with day hospital service in Yamamoto Centre [14], Budapest, Hungary. After inclusion, patients were stratified into a control group and an acupuncture + Booster group. A simple randomization method was performed to create an acupuncture group and a control group. (Embedding acupuncture with MAXON-M Monofilment implantation) [15] and Booster Equipment.[16] After 3 months all patients went for a control to the same rheumatologist specialists as before starting the procedure in the Physiotherapy Department of Yamamoto Institute.

Patients in the Acupuncture+ Booster group

This group of patients had been treated once a month during the whole period of the clinical trial using the permanent dry needling method according to the correct TCM pattern. The period was 3 months of trial. The "time release" dry needling system with the inserted and permanently entered insertion with the help of a special needle was applied. The length of the special stainless-steel needle is 10.8 cm, and the diameter of the lumen is 0.7mm. The threads (MAXOL-M Monofilamentum, USA) were cut into 0.7–1-cm pieces and then applied with the needle. The threads were placed into this needle and the material was applied to the "acupoints". Loco-regional heat (Booster) was applied 2 times a week during treating course. Twelve needles were inserted into every subject per session. The depth of thread insertion was 0.7–0.9 mm. There was no other needle manipulation performed. The insertions of monofilament were applied once a month based on the total absorption time of the previous threads being 4 weeks.

Patients in control group

Physiotherapy in our department, (Institute of Complementary and Alternative Medicine, University of Pecs), as in many rehabilitation centers in Hungary, chronic backache rehabilitation was mainly based on the rheumatic protocol method in an attempt to restore normal movement and improve strength, alleviate pain condition, achieve less rest from work in younger patients. Each patient received certain modalities of treatment (3 times a week: UV, infrared soft laser irradiation, massage) as decided by the supervising senior physiotherapist according to the patient's need at different stages of recovery.

Results

Data collection and analysis

Two authors independently assessed methodological quality and extracted data. The trial was combined using analyses method or levels of evidence. Categorical variables were analyzed using the v2 test or Fisher's exact test for small samples. Measurement data were analyzed using two-tailed t-tests. All recorded data were input using Epi Info software (CDC, Atlanta, GA) and statistically analyzed using SPSS 11.5 statistical software (SPSS, Chicago, IL). For all analyses, p < 0.05 was considered to be statistically significant. Chisquare analysis of the acupuncture+Booster group and control group was also performed to determine homogeneity between both groups in terms of age, gender, and pretreatment measurement outcomes. A subjective index (VAS) from painful condition (1-10) treated and control group, respectively, p < 0.05 at 3 months, and later too was also determined during the follow-up period. The VAS scale was also enhanced in all cases, but the members of the acupuncture+ loco-regional heat by Booster group had more efficient function than the control group in painless condition. In summary, according to the above-mentioned results, changes of the index are better in the acupuncture group than in the control group. The intervention was well tolerated by patients. Any "throw-out reaction" of monofilament and side-effect was not observed under the treatment.

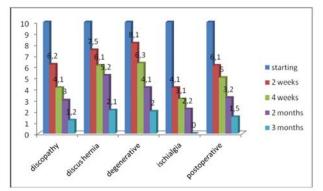


Figure 4. VAS result in different diagnose in treated groups

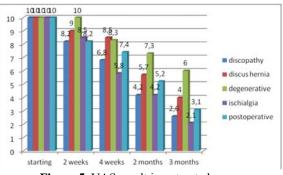


Figure 5. VAS result in untreated group





Figure 6, 7, 8. embedding acupuncture procedure, needle insertion, tissues slide [17]

According to our experience, the holistic treatment of low back pain needs a complex approach in which important points are summarized to take into daily practice as follows:

- Orthostatic correction, no "bed-rest"!
- Postural position improvement
- Developement of muscle ballance
- Motility habilitation
- Sitting, standing, walking, moving exercises- daily performed
- Isometric exercises
- Yoga, Tai-Qi, Qi-Gong, Swimming (on back only!)
- Proper diet (if weight loss is necessary...)
- Ethic treatment choosing, performing with skillfulness
- Neuraltherapy (using less dosage of anaestheticums) [18], [19]
- Acupuncture, proper physio-physicotherapy ("boostering effect")

There is evidence for chronic low-back pain, for pain relief and functional improvement for acupuncture, compared to no treatment or sham therapy. These effects were observed immediately after the end of the sessions and at longer-term follow-up. There is evidence that acupuncture, added to other conventional therapies, relieves pain and improves function better than the conventional therapies alone. However, "dry needling" (special embedded form) and RF non-invasive physiotherapy treatments appear to be a useful adjuncts to other (pharmacological substance) therapies for chronic low back pain, decreasing their dosage avoiding unnecessary side effects. We recognized after trial period during controls to decrease number of medical visit of treated patients and also less oral analgesic's intake (less cost in 35 %). Between the ages of

35-60 there was significant improvement to have less sick-list. Clear recommendations should be made about the most effective acupuncture technique and exact, correct application of RF non-invasive treatment for shortening time of convalescence avoiding improvement of worsening or long-term pain development. (the energy-dosage and technique are important). We find that according to our protocol for "Booster" loco-regional deep heat applied for low back pain group, the required time was 20-25 minutes with 25-Watt power. The positive and negative electrodes can not be connected to avoid burning effect on the skin. There are some contraindications to apply the Booster: Pacemaker, Missing Heat-feeling,Large implantatum, PregnancySignificant big size of Ascites in abdomen (changing conductance of electricity)

Conclusion

The recent data allow firm conclusions about the effectiveness of acupuncture for (sub)acute and chronic low back pain. For chronic low back pain, acupuncture is more effective for pain relief and has more functional improvement than any treatment or sham treatment immediately after treatment and in the longer run. Simple acupuncture is not more effective than other conventional and "alternative" treatments. The data suggest that permanent acupuncture so called "dry-needling" with combination of RF targeted therapy (heat "Boostering") may be useful adjuncts to other therapies for chronic low back pain instead of invasive RF method. [15], [17]. The most important duty is to enhance the quality of life of patients suffering from longer-term pain. We should consider applying any treatment taking into account less necessary intervention, taking longer time of patients for result because most of the studies were of lower methodological quality, there certainly is a further need for higher quality trials in this area. Our results with non-invasive special heat "boostering" application are the following: it is easy to work with the instrument, it was well tolerated by all patients, we noticed additionally positive effects due to treating (according to reports of patients in other accompanying "cold-dampness symptoms" - diseases (COPD, asthma!) The Booster equipment is a product innovation in the field mainly of complementary cancer treatment [20], its use enhances the effect of both chemotherapy and other drugs. This ,,boostering function is developed and used mainly for oncology but it can be successfully used for other medical fields such as rheumatology, neurosurgery, dermatology and analgesic pain-killer therapy.

References

- Streng A., Linde K., Hoppe A., Melchart D. (2007) Acupuncture for chronic pain within the research program of 10 German Health Insurance Funds—Basic results from an observational study- Original Research Article, Complementary Therapies in Medicine, Volume 15, Issue 4, December 2007, Pages 238-246, W. Weidenhammer,
- [2] Peter T. Dorsher (2011) Acupuncture for chronic pain- Original Research Article, Techniques in Regional Anesthesia and Pain Management, Volume 15, Issue 2, April 2011, Pages 55-63
- [3] Thomas K.J., Fitter M., Brazier J., MacPherson H., Campbell M., Nicholl J.P., Roman M. (1999) Longer term clinical and economic benefits of offering acupuncture to patients with chronic low back pain assessed as suitable for primary care management -Original Research Article, Complementary Therapies in Medicine, Volume 7, Issue 2, June 1999, Pages 91-100
- [4] Ammendolia C., Furlan AD, Imamura M, Irvin E, van Tulder M. (2008) Evidence-informed management of chronic low back pain with needle acupuncture -Review Article, The Spine Journal, Volume 8, Issue 1, January–February 2008, Pages 160-172
- [5] Stomski N J, Mackintosh S, Stanley M. (2010) Acupuncturists' perspectives on outcome measures to evaluate acupuncture care for chronic low back pain -Original Research Article, Complementary Therapies in Medicine, Volume 18, Issue 1, February 2010, Pages 28-41 [6] Abbreviations of channels: LU= lung, UB= Urine Bladder, St=stomach, Sp=Spleen-pancreas, K:=kidney, GB= Gall-Bladder, Du= Governor Channel
- [7] Vas J, Aranda J M, Modesto M, Benítez-Parejo N, Herrera A, Martínez-Barquín D M, Aguilar I, Sánchez-Araujo M, Rivas-Ruiz F. (2012) Acupuncture in patients with acute low back pain: A multicentre randomised controlled clinical trial, Original Research Article, PAIN, Volume 153, Issue 9, September 2012, Pages 1883-1889 [8] Classic ear points according to P.Nogiere / IBattlefieldl ear points: Omega2, Shen-Men, Zero, Thalamus, Gyrus Cinguli- according to R. Niemtzow (USA, 2004)
- [9] Feisskohl et al. History of Oncothermia and their devices www.oncothermia-Journal.com Volume 3. pp.64. ISSN 2191-6438
- [10] Ee C C, Manheimer E, Pirotta M V, White A R. (2008) Acupuncture for pelvic and back pain in pregnancy: a systematic review -Review Article, American Journal of Obstetrics and Gynecology, Volume 198, Issue 3, March 2008, Pages 254-259

- [11] Grant D J, Bishop-Miller J, Winchester D M, Anderson M, Faulkner S. (1999) A randomized comparative trial of acupuncture versus transcutaneous electrical nerve stimulation for chronic back pain in the elderly Original Research Article, Pain, Volume 82, Issue 1, 1 July 1999, Pages 9-13
- [12] Itoh K, Itoh S, Katsumi Y, Kitakoji H. (2009) A pilot study on using acupuncture and transcutaneous electrical nerve stimulation to treat chronic non-specific low back pain Original Research Article, Complementary Therapies in Clinical Practice, Volume 15, Issue 1, February 2009, Pages 22-25,
- [13] Meggyeshazi N. et al. (2011) Clinical studies and evidences of moduated RF-conductive heating (oncothermia) methods-review, www.oncothermia-Journal.com Volume 3. pp.57. ISSN 2191-6438 [14] Pecs University outpatient CAM Department in Budapest [15] HegyiG. (2000) Mechanic and electromagnetic biostimulation, Budapest, 2000, Thesis St. Istvan University, Biotechnics Department
- [16] Main features of Booster: Radio-Frequency 13,56 MHz control unit, continuously adjustable startig power of 1 Watt up to 60 Watt, RF tuning about impedance (self focusing), portable, (Oncotherm GmbH, Germany, www.oncotherm.de) [17] Hegyi G, Szigeti Gy. (2012) Rehabilitation of Stroke Patients Using Yamamoto New Scalp Acupuncture: A Pilot Study, The Journal of Alternative and Complementary Medicine, Volume 18, Number 10, 2012, pp. 971–977 a Mary Ann Liebert, Inc.DOI: 10.1089/acm.2011.0047
- [18] Di Cesare A, Giombini A, Di Cesare M, Ripani M, Vulpiani M C, Saraceni V M. (2011) Comparison between the effects of trigger point mesotherapy versus acupuncture points mesotherapy in the treatment of chronic low back pain: A short term randomized controlled trial Original Research Article, Complementary Therapies in Medicine, Volume 19, Issue 1, February 2011, Pages 19-26
- [19] Benjamin R M, Manchikanti L, Parr A T, Diwan S, Singh V, Falco F J, Datta S, Abdi S, Hirsch J A. (2012) The Effectiveness of Lumbar Interlaminar Epidural Injections in Managing Chronic Low Back and Lower Extremity Pain, Pain Physician 2012; 15:E363-E404 • ISSN 2150-1149
- [20] <u>www.oncotherm.org</u>