Immediate Effect of Acupuncture on Post-Operative Pain After Lumbar Surgery

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Immediate Effect of Acupuncture on Post-Operative Pain After Lumbar Surgery

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Prophet Muhammed The Messenger of Allah (PBUH) said, "When a man dies, his deeds come to an end except for three things: ceaseless charity; a knowledge which is beneficial, or a virtuous descendant who prays for him (for the deceased)."

“The only true wisdom is in knowing you know nothing.”

Socrates
Dedication

To The European Union – Erasmus Mendus Program – Alfihri Project

I would not be here if you did not exist.

To my wonderful friends Sarah, Qiaoqiao, Abdulrazzak, Khadija, Dina and Inna thank you for making porto a better place.
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To my family for all their love and support, for letting me follow my dreams all along the way.

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ABSTRACT

Acupuncture has a wide range of possible applications and may be able to contribute to the management of post-operative pain. Moreover, in general, side effects from acupuncture are low. It therefore represents a useful therapeutic option to consider within the overall pain management of individuals.

According to the Heidelberg model of TCM, we designed clinical randomized single blinded controlled trial to investigate if acupuncture can be a useful therapeutic option in post-operative pain after lumbar surgery. To achieve this goal 30 patients were randomly assigned to two groups: Group one: Verum group received acupuncture in three points R10(KI10), V40(BL40) and L6(SP6). Group two: received Sham acupuncture in three points that does not belong to any conduits. Leopard spot technique was the chosen acupuncture technique for both groups, the treatment was given 24 hours after lumbar surgery for two mean pathologies LDD and LSS. The pain assessment was evaluated by subjective measurement by the VAS and objective by measuring the angle of the hip in the straight leg raise test (Modified Laségue Test) to the painful point of active movement, before and after the acupuncture. Our results showed a significant decrease in the pain on VAS by almost half comparing to before the acupuncture in both groups. A significant increase in angle measurement was noted as well between before and after the acupuncture in both groups. By comparing data in both groups we found out that the verum group showed better results than the sham group. However, This difference was not statistically significant $P > 0.005$. A low case number is the most probable cause of not being significant. To achieve a significant difference we need to recruit 38 patients.

Our results confirmed that acupuncture can be used as a post-operative pain analgesic, it also proved the efficiency of the points choice. However, the therapeutic effect found in the control group is not unusual. Sham acupuncture appeared to have an analgesic effect in 40% to 50% of patients compared to 60% to 75% for real acupuncture. This effect can be explained by several theories:

a. In our study we used the leopard spot technique that- according to TCM theory- has a systemic effect on the qi and xue of the body. This can be translated – according to Heidelberg model – as a systemic effect on the vegetative functional balance and microcirculation.
b. Our sham points have common dermatomes with the true acupoints, The noticed effect can therefore be attributed to the segmental acupuncture effect.

c. Researchers stated that sham acupuncture lead to same early pain relief that did not reach statistic significant and then declined thereafter. In our study we evaluated only the immediate effect of acupuncture therefore, a further pain assessment might be necessary to evaluate the sham acupuncture effect.

d. The theory of absence of a specific effect of acupuncture might be argued as well as one of the possible explanations for our results in this group.

In conclusion: Acupuncture showed to be an effective way of treatment in post-operative pain after lumbar surgery for LDD and LSS. No side effects for acupuncture were found in our study. A significant difference was found before and after the acupuncture in patients who were consuming regularly their conventional analgesic medication. The subjective and objective methods of measurements were both improved after acupuncture. Finally, acupuncture can be used effective as an adjunct to conventional analgesia in surgery departments.

Key words: acupuncture, sham acupuncture, post-operative pain, Heidelberg model, lumbar surgery
RESUMO

A acupunctura apresenta uma vasta gama de aplicabilidades, tal como na redução da dor pós-operatória. Para além de possuir uma reduzida percentagem de efeitos secundários, a acupunctura constitui uma opção terapêutica a considerar no manejo da dor em geral. Segundo o modelo de Medicina Tradicional Chinesa de Heidelberg, projetou-se um ensaio clínico randomizado, controlado e simples cego, no sentido de investigar se a acupunctura pode ser uma opção terapêutica válida para a dor pós-operatória após cirurgia lombar. A amostra de 30 pacientes foi randomizada e aleatoriamente dividida em dois grupos: o grupo um (grupo verum) recebeu acupunctura em três pontos R10 (KI 10), V40 (BL40) e L6 (SP6); grupo dois, foi submetido à acupunctura Sham em três pontos que não pertencem a nenhum conduit o. A técnica de acupunctura Leopard foi a escolhida para ambos os grupos e administrada 24 horas após a cirurgia lombar em doentes com estenose espinhal lombar ou discopatia lombar. A avaliação da dor foi subjetivamente determinada segundo a escala analógica visual, e objetivamente, através da medição do ângulo formado entre bacia com a perna em extensão completa e o ponto mais doloroso da flexão ativa da coxa (Teste modificado de Laségue), antes e depois da acupunctura. Ao comparar ambos os grupos, constatou-se que o grupo verum apresentava melhores resultados do que o grupo sham, no entanto, esta diferença não foi estatisticamente significativa P> 0,005.

Os resultados do presente estudo mostraram o comprovado efeito analgésico da acupunctura na dor pós-operatória, assim como, uma eficaz seleção dos acupontos. No entanto, o efeito terapêutico encontrado no grupo de controlo não é incomum. A acupunctura Sham revelou um efeito analgésico na ordem dos 40% a 50% dos pacientes em comparação com 60% para 75% para a acupunctura verum. Este efeito pode ser explicado por várias teorias:

a. A técnica de acupunctura - Leopard tem um efeito sistêmico sobre o qi e xue do. Os pontos sham escolhidos têm dermatomos em comuns com os verdadeiros Investigadores afirmam que a acupunctura sham conduz a um alívio da dor precoce, corpo. pontos de acupunctura, o efeito observado pode, portanto, ser atribuído ao efeito da acupunctura segmentar.sem valor estatístico significativo, e momentos após, este valor declina. No presente estudo, avaliamos apenas o efeito imediato da acupunctura, como tal, sugere-se futura investigação no sentido de avaliar o efeito da acupunctura sham na dor pós-
operatória. atribui-se à teoria da ausência de efeito específico da acupuntura. Outra hipótese nomeada na tentativa de explicar os resultados do grupo sham,

**Em conclusão**: a acupuntura mostrou ser uma forma eficaz de tratamento da dor pós-operatória na cirurgia lombar em doentes com estenose espinhal lombar ou discopatia lombar. Não foram encontrados efeitos colaterais da acupuntura. Verificou-se uma diferença significativa antes e depois da acupuntura em pacientes com hábitos medicamentosos regulares para analgésicos convencionais. Todos os parâmetros subjetivos e objetivos aplicados melhoraram os seus valores após a acupuntura. Por fim, a referir que, a acupuntura pode ser considerada uma opção terapêutica adjuvante eficaz para analgesia em departamentos de cirurgia convencional.

**Palavras-chave**: acupuntura, acupuntura sham, dor pós-operatória, modelo Heidelberg, cirurgia lombar
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<td>MC</td>
<td>Microcirculation</td>
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<td>NK</td>
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<td>NSAID</td>
<td>Nonsteroidal Anti-Inflammatory Drugs</td>
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<td>R - KI</td>
<td>Renal - Kidney</td>
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<td>TCM</td>
<td>Traditional Chinese Medicine</td>
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<td>V - BL</td>
<td>Vesicle – Bladder</td>
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Chapter I
Introduction
Introduction

Chronic low back pain is one of the most common reasons why people seek medical treatment; moreover, the consequent disability creates a great financial burden [1]. It is the second most common pain for which physician treatment is sought and a major reason for absenteeism and disability [2]. Considering direct and indirect costs in terms of health care and lost productivity, the annual cost of low back pain (LBP) to society is staggering [2]. Approximately 5% of the people with low back pain disability account for 75% of the costs associated with low back pain [3].

More than 85% of patients who present to primary care have LBP that cannot reliably be attributed to a specific disease or spinal abnormality. [3] However, in minority of patients, the pain is caused by a specific disorder, such as Cancer, infection or fracture. Spinal stenosis and symptomatic disc herniation are present in about 3% and 4% of patients respectively. [3]

In this master thesis we will be dealing with these two last pathologies. As in many cases with neurological symptoms or failure of medical treatment, surgery remains the only choice. Although several surgical techniques aim to reduce the post-operative recovery, the post-operative pain management remains a significant challenge for healthcare professionals. Many patients experience pain after surgery, with about 86% reporting moderate, severe or extreme pain [4].

Opioid analgesics are the main component in post-operative pain however, they are associated with undesirable side-effects including nausea, vomiting, pruritus, sedation, dizziness and decreased gut motility.[4] Consequently, the use of adjunct analgesic that provide opioid-sparing effects and decrease the incidences of opioid related side effects is therefore needed. [4]

Acupuncture is mostly known for its analgesic effects. A German study [5] found that acupuncture decreased both pain intensity and opioid consumption up to 72 hours after surgery. Many studies suggested several points and intervals after the operation.

The general purpose of this thesis is to evaluate the therapeutic effect of acupuncture in relieving post-operative pain. For this purpose we developed an experimental study, prospective, controlled, randomized, and single blinded to evaluate the acute effects of acupuncture on post-operative lumbar surgery
In this clinical study, our specific objectives were defined as followed:

+ To develop a clinical protocol for the treatment of post-operative pain after lumbar surgery.

+ To create a study design for the objective assessment of acupuncture effects in this condition.
II/ Lumbar Spine

1. Normal Anatomy:

The spine is made of 33 vertebrae. When viewed from the side, an adult spine has a natural S-shaped curve; cervical lordosis, thoracic kyphosis, lumbar lordosis and sacrococcygeal kyphosis. [6]. The main purpose of the curves is to maintain balance, to absorb shocks and to allow range of motion throughout the spinal column. [7]

From L1 to L5, the posterior aspect changes from slightly concave to slightly convex, and the diameter of the cylinder increases gradually because of the increasing loads each body has to carry. At the upper and lower surfaces, two distinct areas can be seen: each has a peripheral ring of compact bone – surrounding and slightly above the level of the flat and rough central zone – which originates from the apophysis and fuses with the vertebral body at the age of about 16. The central zone – the bony endplate – shows many perforations, through which blood vessels can reach the disc.

Figure 1 Spine Anatomy – According to Netter
A layer of cartilage covers this central zone, which is limited by the peripheral ring. This is the cartilaginous endplate, forming the transition between the cortical bone and the rest of the intervertebral disc. A sagittal cut through the vertebral body shows the endplates to be slightly concave, which consequently gives the disc a convex form. [6] From L1 to L5, the pedicles become shorter and broader, and are more lateral. This narrows the anteroposterior diameter and widens the transverse diameter of the vertebral canal from above downwards. Together with the increasing convexity of the posterior aspect of the vertebral body, these changes in the position of the pedicles alter the shape of the normal bony spinal canal from an ellipse at L1 to a triangle at L3 and more or less a trefoil at L5. [6]

Each lamina is flat and broad, blending in centrally with the similarly configured spinal process, which projects directly backwards from the lamina. The two transverse processes project laterally and slightly dorsally from the pediculolaminar junction. The superior and inferior articular processes originate directly from the lamina [6].

1.1. Intervertebral Disc:

Two adjacent vertebral bodies are linked by an intervertebral disc. Together with the corresponding facet joints, they form the ‘functional unit of Junghans’ [6] [8]. The primary function of the disc is to join the vertebrae and allow movement between them. The other functions are typical of the erect spine: a shock absorber; a load distributor; and a separator of the posterior facets to maintain the size of the intervertebral foramen. The disc consists of an annulus fibrosus, a nucleus pulposus and two cartilaginous endplates. The distinction between annulus and nucleus can only be made in youth, because the consistency of the disc becomes more uniform in the elderly. An upper and a lower cartilaginous endplate (each about 0.6–1 mm thick) cover the superior and inferior aspects of the disc. They are plates of cartilage that bind the disc to their respective vertebral bodies. Each endplate covers almost the entire surface of the adjacent vertebral body; only a narrow rim of bone, called the ring apophysis, around the perimeter of the vertebral body is left uncovered by cartilage. The endplate permits diffusion and provides the main source of nutrition for the disc.[9] Up to the age of 8
years, the cartilaginous endplates are penetrated by blood vessels which pass into the peripheral layers of nucleus and annulus. Thereafter, the disc’s nutrition is achieved by diffusion through the endplate. The hyaline endplate is also the last part of the disc to wear through during severe disc degeneration. the annulus fibrosus is made up of 15–25 concentric fibrocartilaginous sheets or ‘lamellae’, each formed by parallel fibres, running obliquely at a 30° angle between the vertebral bodies. Because the fibres of two consecutive layers are oriented in opposite directions, they cross each other at an angle of approximately 120° disc great strength against shearing and rotational stresses [10], while angular movements remain perfectly possible. The nucleus pulposus consists of a gelatinous substance, made of a meshwork of collagen fibrils suspended in a mucoprotein base which contains mucopolysaccharides and water. At birth the nucleus pulposus occupies the center of the intervertebral space. As the anterior part of the vertebral body grows faster than the posterior part, the nucleus comes to lie more posteriorly. Consequently, the anterior part of the annulus will have thicker and stronger fibers [11], which means that the annulus gives better protection against anterior than posterior displacements of the nucleus; this is disadvantageous with respect to the contiguous nerve roots and dura[8].

1.2. Ligaments:

The broad, thick anterior longitudinal ligament originates from the anterior and basilar aspect of the occiput and ends at the upper and anterior part of the sacrum. It consists of fibers of different lengths: some extend over 4–5 vertebral bodies; the short fibers attach firmly to the fibers of the outermost annular layers and the periosteum of two adjacent vertebrae.

*The posterior longitudinal ligament* is smaller and thinner than its anterior counterpart: 1.4 cm wide (versus 2 cm in the anterior ligament) and 1.3 mm thick (versus 2 mm). This is another fact in favor of the theory that the lumbar spine was originally designed to be a horizontal hanging structure: to withstand extension strains, the back had to be stronger anteriorly than posteriorly [9].

*The ligamentum flavum* connects two consecutive laminae and has a very elastic structure with an elastin content of more than 80%. *The interspinous ligament* lies
deeply between two consecutive spinal processes. Unlike the longitudinal ligaments, it is not a continuous fibrous band but consists of loose tissue with the fibers running obliquely from posterosuperior to anteroinferior. The supraspinous ligament is broad, thick and cord-like. It joins the tips of two adjacent spinous processes, and merges with the insertions of the lumbodorsal muscles. The intertransverse ligaments are thin membranous structures joining two adjacent transverse processes. The iliolumbar ligaments are thought to be related to the upright posture. They do not exist at birth but develop gradually from the epimysium of the quadratus lumborum muscle in the first decade of life to attain full differentiation only in the second decade [8] [9].

1.3. Muscles and fascia:

The spine is unstable without the support of the muscles that power the trunk and position the spinal segments [12]. Back muscles can be divided in four functional groups: flexors, extensors, lateral flexors and rotators. The extensors are arranged in three layers: the most superficial is the strong erector spinae or sacrospinalis muscle. The middle layer is the multifidus. The fibers of the multifidus are centered on each of the lumbar spinous processes. The third layer is made up of small muscles arranged from level to level, which not only have an extension function but are also rotators and lateral flexors. The flexors of the lumbar spine consist of an intrinsic (psoas and iliacus) and an extrinsic group (abdominal wall muscles). The lateral flexors and rotators are the internal and external oblique, the intertransverse and quadratus lumborum muscles[7].

1.4. Spinal Canal:

The spinal canal is made up of the canals of individual vertebrae so that bony segments alternate with intervertebral and articular segments. The shape of the transverse section changes from round at L1 to triangular at L3 and slightly trefoil at L5. The margins of the canal are formed by an anterior wall and a posterior wall, connected through pedicles and intervertebral foramina[13].
The anterior wall consists of the alternating posterior aspects of the vertebral bodies and the annulus of the intervertebral discs. In the midline these structures are covered by the posterior longitudinal ligament, which widens over each intervertebral disc. The posterior wall is formed by the uppermost portions of the laminae and the ligamenta flava. Because the superoinferior dimensions of the laminae tend to decrease at the L4 and L5 levels, the ligamenta flava consequently occupy a greater percentage of the posterior wall at these levels. The posterolateral borders of the posterior wall are formed by the anterior capsule of the facet joint and the superior articular process, which is located well anterior of the articulating inferior articular process. The spinal canal contains the dural tube, the spinal nerves and the epidural tissue [6] [13].

1.5. **Nerve roots**:

The spinal cord terminates at the level of T12–L1. Consequently the lower lumbar and sacral nerve roots must run within the vertebral canal. The motor (ventral) and dorsal (sensory) rootlets that take their origin in an uninterrupted series of attachments at the ventrolateral and the dorsolateral aspects of the cord, run freely downwards through the subarachnoid space of the dural sac. For clinical purposes it is as well to divide the components of the nerve root into an external aspect (the sheath), which is mobile and is responsible for pain, and an internal aspect (the nerve fibers), which serves conduction only. This helps to distinguish the symptoms and signs of each, so permitting proper assessment of the location of a lesion, the magnitude of compression and the degree of functional incapacity [7][14].
2. **Pathological Anatomy**:

The normal anatomical relationships described above may be altered by the development of pathological states, in any part of the nerve root canal or the intervertebral foramen, which produce compressive lesions that may cause symptoms. The changes which may occur in readily recognizable clinical conditions [15]. However, we will describe briefly the lumbar disc disease and the lumbar spine stenosis together with the surgical techniques that will be illustrated.

2.1. **Lumbar Disc Disease**:

2.1.1. **Background**: Lumbar disc disease is the most common cause of sciatica. It accounts for a large amount of lost productivity in the workforce. Accurate diagnosis can be difficult and often requires interpretation. In approximately 90% of the cases, sciatica is caused by a herniated disc involving nerve root compression. In the absence of red flags, the initial approach to treatment is conservative and includes physical therapy and analgesic medications. In
90% of patients, acute attacks of sciatica improve within 4 to 6 weeks without surgical intervention[16].

2.1.2. **Physiopathology**: A herniated disk fragment comes from the nucleus pulposus of the disc (a remnant of the embryonic notochord). In the normal condition, this nucleus is in the disk center securely contained by the annulus fibrosus. When a fragment of nucleus herniates, it irritates and/or compresses the adjacent nerve root. This can cause the pain syndrome known as sciatica and, in severe cases, dysfunction of the nerve[17].

2.1.3. **Clinical Presentation**: Most lumbar disc herniations (lumbar disc diseases) are preceded by bouts of varying degrees and duration of back pain. In many cases, an inciting event cannot be identified. Pain eventually may radiate into the leg. It may be characterized as less achy, burning, or similar to an electrical shock and is often described as a shooting or stabbing pain. The distribution of the leg pain is somewhat dependent on the level of nerve root irritation. Higher herniations (third or fourth lumbar levels) can radiate into the groin or anterior thigh. Lower radiculopathies (first sacral level) cause pain in the calf and bottom of the foot.[17]

2.1.4. **Clinical Examination**: On examination, patients may be neurologically normal, may have a profound radiculopathy, or may even demonstrate a cauda equina syndrome. A positive straight-leg raising sign is almost always present. However, a crossed straight-leg raising sign may be even more predictive of a lumbar disc herniation. The back may appear scoliotic. Gait is often abnormal. Muscle weakness may be revealed particularly when testing walking on heels and toes.[16]

2.1.5. **Surgical Indications**: Experts agree that cauda equina syndrome is an absolute indication for urgent surgical intervention. Most also would consider surgery for patients with progressive or severe neuromotor deficit, although
no controlled studies exist to support this recommendation. If surgery is necessary, discectomy to relieve nerve compression is the current standard of care[18] [17].

2.1.6. **Surgery** : The first published report of lumbar disc disease with radiculopathy was written by Mixter and Barr in 1934. Surgical treatment was not widespread until the 1950s. Today, lumbar discectomy is one of the most commonly performed elective operations in the United States [18]. Microdiscectomy produced comparable results to standard open discectomy. The reviewers concluded that, for patients with sciatica caused by lumbar disc prolapse, surgery provides faster relief from the acute attack than conservative management; long-term differences in outcome are unclear. A more recent systematic review of 5 studies that compared surgery with conservative management of sciatica concluded that early surgery provides better short-term relief of sciatica but no benefit after 1 or 2 years.[16]

2.2. **Lumbar Spinal Stenosis** :

2.2.1. **Background** : Approximately 250,000-500,000 US residents have symptoms of spinal stenosis. This represents about 1 per 1000 persons older than 65 years and about 5 of every 1000 persons older than 50 years. lumbar spinal stenosis (LSS) is a leading cause of pain, disability, and loss of independence in older adults. The prevalence and economic burden of LSS is growing exponentially due to the aging population. It is a chronic disease caused by age related degenerative narrowing (stenosis) of the spinal canal that can lead to compression and ischemia of the spinal nerves (neuroischemia). Spinal stenosis is part of the aging process, and predicting who will be affected is not possible. No clear correlation is noted between the symptoms of stenosis and race, occupation, sex, or body type. The degenerative process can be managed, but it cannot be prevented by diet, exercise, or
lifestyle. Progressive narrowing of the spinal canal may occur alone or in combination with acute disc herniations. Congenital and acquired spinal stenosis places the patient at a greater risk for acute neurologic injury [19].

2.2.2. **Physiopathology:** The pathophysiology of spinal stenosis is related to cord dysfunction elicited by a combination of mechanical compression and degenerative instability. With aging, the intervertebral disk degenerates and collapses, leading to spur formation. Alternatively, the caudal vertebral body superior articulating process contributes to lateral recess and foraminal stenosis. Indeed, facet hypertrophy between L4 and L5 vertebrae may impinge the L4 nerve root in the foramen and the L5 proximal nerve root sheath in the lateral recess. The 2 lower motion segments (L3-L4, L4-L5) are most commonly affected by degenerative stenosis. These segments are in a transition zone from the rigid sacrum to the mobile lumbar spine. In addition, the posterior joints in this area have less of a sagittal orientation, which affords more rotation and are therefore more vulnerable to rotatory strains. Lumbar spinal stenosis (LSS) implies spinal canal narrowing with possible subsequent neural compression. Although the disorder often results from acquired degenerative changes (spondylosis), spinal stenosis may also be congenital in nature. In some cases, the patient has acquired degenerative changes that augment a congenitally narrow canal. The canal components that contribute to acquired stenosis include the facets (hypertrophy, arthropathy), ligamentum flavum (hypertrophy), posterior longitudinal ligament . vertebral body (bone spurs), intervertebral disk, and epidural fat. Congenital stenosis may predispose an individual with mild degenerative changes to become symptomatic earlier in life[20].

2.2.3. **Clinical Presentation [19]:** The clinical syndrome of LSS is known as neurogenic claudication. It is characterized by bilateral or unilateral buttock, lower extremity pain, heaviness, numbness, tingling or weakness, precipitated by walking and standing and relieved by sitting and bending forward . Lower
back pain is not necessarily associated with neurogenic claudication. Limited walking ability is the dominant functional impairment caused by LSS.

2.2.4. **Surgical indications**: Surgery for lumbar spinal stenosis should only be considered if a patient’s ability to participate in everyday activities is unacceptably reduced and a concerted effort to relieve symptoms through non operative means has been unproductive.

2.2.5. **Surgery**: Lumbar laminectomy, the most common surgery for spinal stenosis has a high success rate. Also in most cases lumbar decompression surgery allows people to return to a more active and pain free lifestyle. **Foraminotomy**: If part of the disc or a bone spur (osteophyte) is pressing on a nerve as it leaves the vertebra (through the foramen), a foraminotomy may be done. **Laminotomy**: A laminotomy makes a larger opening, this time in the bony plate protecting the spinal canal and spinal cord (the lamina). The lamina may be pressing on the nerve, so the surgeon may make more room for the nerves using a laminotomy [21][22].

3. **Post-Operative Pain Management in Spine Surgery**:

There are many modalities that may provide safe and effective postoperative analgesia. We discuss mainly systemic (e.g. opioids, nonsteroidal anti-inflammatory agents) analgesic options. They still remain the most widely used method for providing pain relief in acute surgical situations. The exact choice or combination of analgesics utilized for a particular patient will depend on the risk benefit profile and patient preferences.

3.1. **SYSTEMATIC ANALGESIC THERAPY**:
3.1.1. *Nonsteroidal anti-inflammatory agents (NSAIDs).*

NSAIDs are a major systemic pharmacological option, providing analgesia without the potential for dependence or addiction but limited by a therapeutic ceiling. These agents inhibit central and peripheral cyclooxygenase (COX) enzymes and production of prostaglandins, resulting in attenuation of inflammation and a decrease in the mediators of nociception. NSAIDs have also spinal mechanism of action. When used as an adjunct to opioids, NSAIDs may improve postoperative analgesia, reduce opioid requirements, facilitate return of gastrointestinal function, reduce nausea, decrease respiratory depression and improve patient satisfaction. However, NSAIDs are associated with a number of side effects, including decreased hemostasis, renal dysfunction, gastrointestinal hemorrhage, and adverse effects on bone healing. NSAID-induced platelet dysfunction and inhibition of thromboxane-A2 causes decreased hemostasis [23][25].

3.1.2. *PARACETAMOL AND METAMIZOLE*

Nevertheless they are often considered as NSAIDs, metamizole and paracetamol do not inhibit the COX enzymes at the analgesic concentrations and have no anti-inflammatory activity. They have central anti-nociceptive effects involving serotonergic descending inhibitory pathways. They do not show the typical side effects of NSAIDs on the gastric mucosa and blood platelets. The risk of agranulocytosis after administration of metamizole or paracetamol is minimal, and so is the related mortality. The efficacy of NSAIDs to paracetamol were shown to be comparable in postoperative pain from major surgery. Adding an NSAID to paracetamol may further improve postoperative pain but, on the contrary, adding paracetamol to NSAIDs had no beneficial effect on analgesia[26].

3.1.3. *KETOROLAC*
Ketorolac is a non-opioid analgesic that has properties similar to those of acetysalicylic acid and ibuprofen. In contrast to opioids, which blunt the perception of pain via its action in the central nervous system, ketorolac prevents pain by acting on the site of injury[24].

3.1.4. **OPIOIDS**:

Opioids remain a central option in the management of moderate to severe perioperative pain. They act peripherally on injured tissues to reduce inflammation, in the dorsal horn of spinal cord to diminish transmission of the nociceptive signal, and in the brain to activate inhibitory pathways of the spinal processing of "pain" signals. Opioids inhibit m receptors, which are distributed both centrally and peripherally, and accordingly account for both the analgesic efficacy and side effects associated with these medications. Opioids depress the respiratory rate and tidal volume by decreasing the responsiveness of the respiratory centers in the pons and medulla oblongata. Tramadol is a synthetic opioid which exhibits weak m- and k receptor agonist activity (10% of morphine potency). compared to traditional opioids, tramadol has been shown to be an efficacious analgesic agent for the treatment of moderate postoperative pain. Dizziness, drowsiness, sweating, nausea, vomiting, dry mouth and headache are commonly reported side-effects [23].

3.2. **NONPHARMACOLOGIC INTERVENTIONS**

In addition to administering analgesics, a combination of various nonpharmacologic interventions should be implemented (e.g., repositioning, applying an ice package to a patient’s forehead, and repositioning the bed so that the patient can have a better visual contact with the nursing staff). Those interventions can improve patients’ responses to pain management by changing their perceptions of pain, altering pain behavior, and providing patients with a greater sense of control over pain [24].
3.3. **ACUPUNCTURE**

Acupuncture, a component of traditional Chinese medicine, is a well-known and widely used treatment for pain and other conditions that has been employed in China for more than 3000 years. There have been increasing numbers of clinical trials evaluating the efficacy of acupuncture and related techniques as an adjuvant method for postoperative analgesia. Therefore, we performed this scientific prospective study to quantitatively evaluate the available evidence for the efficacy of acupuncture and related techniques in postoperative pain management in lumbar surgery [27].
III. Acupuncture

1. Background

Acupuncture literally means to puncture with a needle. Acupuncture originated in China many centuries ago and soon spread to Japan, the Korean peninsula and elsewhere in Asia. Acupuncture is widely used in health care systems in the countries of this region; it is officially recognized by governments and well received by the general public.[28]

The first document that unequivocally described an organized system of diagnosis and treatment which is recognized as acupuncture is The Yellow Emperor’s Classic of Internal Medicine, dating from about 100 BCE. The information is presented in the form of questions by the Emperor and learned replies from his minister, Chhi-Po. The concepts of channels (conduits or conduits) in which the Qi (vital energy or life force) flowed are well established by this time, though the precise anatomical locations of acupuncture points developed later. Acupuncture continued to be developed and codified in texts over the subsequent centuries and gradually became one of the standard therapies used in China [29].

Acupuncture techniques comprise different procedures such as pressure on acupuncture points (acupressure), use of needle insertion, applying heat usually with Artemisia (moxibustion) (Porkert M. a., 1995), combined with electric stimulus on the needle (electro acupuncture) (Bastos, 1993), use of laser (Litscher G. a., 2012). The divergent strands of acupuncture theory and practice were brought together in a consensus known as traditional Chinese medicine (TCM) [30], which also included herbal medicine.

Acupuncture research institutes were established in the 1950s throughout China and treatment became available in separate acupuncture departments within Western-style hospitals. Over the same period, a more scientific explanation of acupuncture was sought by Prof. Han in Beijing who undertook ground-breaking research on acupuncture’s release of neurotransmitters, particularly opioid peptides [29].

2. The system of channels or conduits [31]
According to TCM theory the energy (Qi) flows through channels that are named as Conduit that present a “connection of a group of points with effect on the clinical signs associated with a certain vegetative function, believed to serve as a conduit for the flow of qi and xue. [32] There exists a hierarchy within the conduit system. This consists of Cardinal Conduits or “Cardinales”. [33]

There are twelve, the “Twelve Cardinal Conduits”. They constitute the central supporting structure of the system of conduits. They are symmetrical conduits, in other words they extend in mirrored symmetry over the right and left halves of the body - 3 sinarteria leading from the hand to the chest, and 3 sinarteria mounting from the foot to the upper body.

To these are added [34]:

Twelve Paracardinal Conduits (sinarteriae paracardinales, jingbie). Eight Odd Cardinal Conduits (cardinales impares, qijing bamo, abbreviated to “Odd Conduits”). These cardinal conduits include the leading and responding sinarteries (sinarteriae regens et respondens, dumo and renmo) extending along the median lines of the body. They are complemented by various ramifications which – as their name indicates – produce further imbrications, netlike interconnection of the entire system.

Fifteen Reticular Conduits (sinarteriae reticulares, luomo). Parareticular Conduits (“Reticular Branch Conduits”, sinarteriae parareticulares, bieluo) And finally Reticulars of the Third Generation (reticulares parvulae, sunluo)
3. **Safety** [28]

Generally speaking, acupuncture treatment is safe if it is performed properly by a well-trained practitioner. Unlike many drugs, it is non-toxic, and adverse reactions are minimal. This is probably one of the chief reasons why acupuncture is so popular in the treatment of chronic pain in many countries. However, few rules should be done in order to assure a safe acupuncture treatment. Basically; patient should be treated supine, single use needles are mandatory and finally practitioners must take great care to prevent avoidable cases of infection by washing the hands before treatment.

4. **Availability**: The availability and practicability of acupuncture are also important factors to consider. The advantages of acupuncture are that it is simple, convenient and has few contraindications.

5. **Body Measurements of Acupuncture** [35]
In Chinese medicine, acupuncture measurements are taken individually. Since everyone's body is of a different size and shape, using a person's inborn measurement system, called Cun, makes finding the points more accurate. Therefore, measuring distances in the body surface must be adjusted to the patient size. The cun (Chinese: 寸) is a traditional Chinese unit of length. Its traditional measure is the width of a person's thumb at the knuckle, whereas the width of the two forefingers denotes 1.5 cun and the width of all fingers side-by-side is three cuns. In this sense, it continues to be used to chart acupuncture points on the Acupuncture points.

![Body measurement in Acupuncture](image)

Figure 4: Body measurement in Acupuncture—According to tcmstudent.com

6. **Clinical evaluations** : [28]

Although acupuncture was introduced to Europe as long ago as the early seventeenth century, skepticism about its effectiveness continues to exist in countries where modern western medicine is the foundation of health care, especially in those where acupuncture has not yet been widely practiced. Unlike the evaluation of a new drug, controlled clinical trials of acupuncture are extremely difficult to conduct, particularly if they have to be blind in design and the acupuncture has to be compared with a placebo. Various “sham” or “placebo” acupuncture procedures have been designed, but they are not easy to perform.

To date, modern scientific research studies have revealed the following actions of acupuncture:

- Inducing analgesia
• Protecting the body against infections
• Regulating various physiological functions.

In reality, the first two actions can also be attributed to the regulation of physiological functions. The therapeutic effects of acupuncture are thus brought about through its regulatory actions on various systems, so that it can be regarded as a nonspecific therapy with a broad spectrum of indications, particularly helpful in functional disorders. Although it is often used as a symptomatic treatment (for pain, for instance), in many cases it actually acts on one of the pathogenic links of a disease.

In recognition of the increasing worldwide interest in the subject, the World Health Organization (WHO) conducted a symposium on acupuncture in June 1979 in Beijing, China. Physicians practicing acupuncture in different countries were invited to identify the conditions that might benefit from this therapy. The participants drew up a list of 43 suitable diseases.

7. **Effect of Acupuncture**

Acupuncture has been accepted to effectively treat various diseases, particularly chronic pain. Despite the involvement of psychological factors in acupuncture treatment of patients and stress in animal behavioral tests, a large volume of evidence clearly demonstrates that acupuncture analgesia has physiological, anatomical and neurochemical bases [36]. In table 1 we mentioned 19 different studies which proved their specific effects.

| Table 1: Studies showing specific effect for acupuncture |

This new / old knowledge of traditional Chinese medicine makes it possible today to accept several mechanisms to explain the action of Acupuncture:

a. Energetic mechanism: This corresponds to the classical conceptions of energy Pathways or so-called channels or conduits.

b. Humoral mechanism: It refers to the production of substances; Endogenous opiates play important roles in analgesic acupuncture [37]. In the 1970s and early 1980s, acupuncture was regarded as a novel pain-killer. Naloxone, an antagonist to opiate (morphine-like substrate), was shown to attenuated analgesic action of acupuncture in humans (Mayer1977) and mice (Pomeranz and Chiu, 1976); the release of morphine-like substrate in central nerve system (CNS) was hypothesized to be a possible mechanism. In addition to opioids, there is a role of central monoaminergic systems on acupuncture. Particular emphasis is given to serotonin. Serotonin (5-HT, 5-hydroxytryptamine) was speculated to be an analgesic transmitter in an early study.
With 2Hz EA, threshold of tail pressure pain was shown to increase in SD rats. This analgesic effect diminished after p-chlorophenylalanine (serotonin synthesis inhibitor) injection (Tsai et al., 1989a). Therefore, serotonin is thought to have a role in acupuncture. Evidence suggests that serotonin levels increase in spinal cord (Tsai et al., 1989b) and that its precursor (5-hydroxytryptophan) responds to enhanced analgesia at 2Hz EA (Chang et al., 2004).

c. Modulation of Nociception: Combined with the serotonin theory discussed above, it is hypothesized that the descending inhibitory pathway terminates at the enkephalinergic interneurons; these interneurons release enkephalin which is bound to opioid receptors on spinal cord C-fibers; upon presynaptic binding with enkephalin, C-fibers reduce the amount of excitatory amino acid release, resulting in an anti-hyperalgesic effect. Electric Acupuncture can facilitate this pathway.

d. Inflammatory Reflex: Recently, more and more experts pay attention to inflammation. It has been shown that long term EA reduces activities of T and B cell in the lymph nodes of collagen-induced arthritic (CIA) mice (Yim et al., 2007). In another study, the activity of splenic natural killer (NK) cells in mice was enhanced after long term EA. EA seems to be an immune modulator. This effect is eliminated by β-endorphin antagonist (naloxone) injection (Yu et al., 1998). In a hyperalgesic animal model, inflammatory responses (edema and hyperalgesia) are reduced by Electric Acupuncture (Zhang et al., 2004b; Choi et al., 2005; Zhang et al., 2005a).

8. Acupuncture, with the Leopard spot technique, as a special technique to influence xue

Acupuncture, as leopard spot technique, is a method of therapy that is difficult to explain in modern terms. A side from the traditional theoretical basis for these treatments in letting out calor and excess factors, a key issue is whether it actually produces the claimed effects. Many western acupuncturists have stated informally that they get dramatic results from this treatment method, but, unfortunately, there is no evidence presented to support such contentions. Despite the frequent mention of treating peripheral points by this technique in both ancient and modern Chinese medical texts, there is little reference to it in Chinese medical journal reports. Very few articles focus specifically on use of this technique. While standard acupuncture therapy is depicted as being effective, in part, by releasing various transmitter substances (i.e., endorphins), by stimulating local blood flow (i.e., by dilating vessels), and by producing changes in the brain that may have both systemic and highly specific effects, letting out a small amount
of blood (usually just few drops) remains without a suitable explanation for the potent
effects claimed. The technique used to let out the blood is one of quick and light pricking
to pierce the skin and vein. The Leopard Spot technique has four major therapeutic aims
that are useful in the clinical arena : [31][38]

1- It can invigorate the smooth flow of qi and xue according to the theory of TCM , thereby
picking up and facilitating its flow when the qi and xue need invigoration. Improving circulation
and preventing xue from remaining stagnated;

2. It disperses qi and xue stasis, as in cases of backache or spider veins

3. It can drain excess, calor and ardor. Such excess includes pathogenic factors as in an
invasion of Calor-Venti in the Pulmonary conduit that produces a fever and extremely sore
throat;

4. Finally, bleeding can bring down yang rising, as in the varieties of high blood pressure
due to Hepatic yang rising.

IV. Heidelberg Model of TCM “ TCM as a novel Vegetative Medicine”

1. Background

TCM is a system of findings and sensations designed to establish the functional vegetative state
of the body; this state may be treated by i.e. Chinese pharmacology, acupuncture, Chinese
manual therapy (Tuina), Qigong, or dietetics. A study published in 1989 by Kroenke and
Mangelsdorf demonstrated that 85% of patients complaints in the out-patient clinic cannot be
correlated to a measurable lab finding [40].
This large number of unexplainable complaints is suggested to derive from psychosomatic disorders. As much as 60-80% of chronic ill patients with unexplainable symptoms search for help in complementary medicine[41]. The integration of Chinese medicine into the western world has three important steps:

1- A rational concept of TCM Model.
2- Scientific proof of efficacy and safety.
3- Quality control.

In order to reach the rational approach of Chinese medicine, Professor Greten developed the Heidelberg Model of TCM as scientific model with precise Latin terminology based on Professor Porkert previous sino-studies (Porkert 1983, Porkert, M. 1974, Porkert M. a. 1995) relying on primary Chinese literature.

Based on the first book of mankind (the I Ging), Leibniz Developed the binary numbering system which enables to describe the circular process. Even before the cirurgia Lombaryellow emperor's classic, there is evidence that in classical china, these regulatory fluctuations where described by circulatory function in a simple manner resembling a sinus wave. This wave is part of the so-called monad (Leibniz) or Taiji sign.
Most of the regulatory processes describe periodical fluctuations of the actual value around a target value. Accordingly as vegetative system is a regulatory process; the symptoms are categorized leading to ORB “Group of diagnostically relevant signs that indicate the functional state of a body region, which correlates the functional properties of a conduit”.

The technical and regulatory dimension of Yin/Yang and the evolutionary phases (EP), i.e., Wood, Fire, Earth, Metal, Water, can be seen in an analogous example of the regulation of temperature in a water basin by a thermostat system. Due to the inherent fluctuations, the actual temperature value moves around the set point approximately in a sinus wave.
Heidelberg Model of TCM hypothesizes a relation between this sinusoidal-pattern and the autonomic nervous system activities and it is major molecular effects (hormones, neurotransmitters).

This theory is supported by several scientifically proofed studies all using the Heidelberg Model as backbone and common ground to drown conclusions regarding their respective objectives. Some of these studies are; pain following tonsillectomy Sertel, et al., 2009), Gait improvement (Hauer K. 2011), Qigong effects (Sousa, et al., 2012), polyneuropathy (Schroeder, Lieper, Remppis, & Greten, 2007), walking distance in peripheral occlusive disease (Forschungsemeinschaft, 2006).

Figure 8 : model of system biology [32]

2. Mechanisms to become sick in Heidelberg Model of TCM :

1- Excess of an Agent
2- Problem of transition from one phase to the next
3- Imbalance of antagonist between phases
4- Yin deficiency (in our example of water Basin Yin deficiency means less water causing high variation of the temperature)

3. The functional TCM diagnosis has 4 components:

1- Constitution: a tendency to express the signs of one orb predominantly so that they show in the physical phenotype.
2- Agent: a pathogenic factor eliciting specific signs and symptoms. These may resemble and therefore promote orb patterns. There are external; internal and natural agents.

<table>
<thead>
<tr>
<th>External Agents</th>
<th>Internal Agents</th>
<th>Neutral Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventus('wind'), algor ('cold'), humour ('humidity'), ariditas ('dryness'), aestus ('summer heat'), ardour ('glow')</td>
<td>Ira('anger'), voluptas ('lust'), cogitatio('excessive thinking'), maeror ('grief'), solicitudo('worriedness'), timor('anxiety'), pavor ('shock')</td>
<td>Overwork, malnutrition, trauma, infections.</td>
</tr>
</tbody>
</table>

3- Orb: a group of diagnostically relevant signs indicating the functional state of body island (body region) which correlates with the functional properties of a conduit.

4- Guiding criteria (GC): main interpretation- matrix of symptoms in TCM, based on four regulatory models of physiology

- 1st GC – Repletion (fullness)/ depletion (emptiness) originates from qi, orbs, phases in TCM and corresponds to neuro-vegetative signs in western medicine. Repletion indicates too much qi or blockage of the flow causing excess in the pre blocked area, in general the symptom is worse with pressure, excitation of activating mechanisms as opposed to depletion which indicates lack of qi, amelioration of the symptoms by pressure and indicates lack of activation and/or excess of deactivation)
- 2nd GC - Calor( heat)/ Algor (cold) in TCM evaluates effects of xue ('blood' functional capacity bonded to body fluids with functions such as warming, moisturizing, creating qi
and nourishing a tissue.) and in western medicine refers to signs originated from the humoro-vegetative system, referring to the effects of microcirculation, therefore increased xue activation-increase in microcirculation is called calor, and lack/diminished microcirculation-xue represents algor.

- 3rd GC – Extima (exterior)/Intima (interior) describes the course of a disease caused by an exterior agent invading the body. Most important model within TCM is the model of the six stages (Shan Han Lun). In western medical view this is interpretation of clinical signs predominantly induced by Neuro-immunological mechanism.

- 4th GC - Yin/Yang- evaluates the signs according to TCM to distinguish between primary deregulation (yang) and secondary deregulation due to structural deficiency (yin). If a functional tissue is deficient, there will be excess over regulation to achieve appropriate function, thus leading to exertion of tissue function and function deficiency. In western medicine-a deficient tissue can be vegetatively over stimulated causing signs of repletion-after the exertion signs of depletion will occur-so in this case yin represent deficiency of functional tissue, 37 structural, and/or deficiency of xue (microcirculation), deficiency of body fluids, lack/deficit of jing (cell nucleus- gene). And yang – symptoms are more related to the functional aspect, not with the structure.
4. **Algor as a pathogenic factor:**

In the HD model algor, from a humoro-vegetative perspective, defined as locally reduced MC (capillary blood flow) in a certain tissue. Clinically it is associated with signs and symptoms as if they had been exposed to cold environment, such as skin cold, stiff muscles, and excruciating pain localized to the gradual emergence. Algor is a pathogenic factor of yin nature, which leads to contraction and stagnation, an a functional deficiency of the affected tissue.

**Types of algor:**

There are four different types of Algor

a. **Algor algor:**
   describes a local reduction of MC after exposition to cold environment due to a physiological vasospasmic reflex, which helps to keep the body core temperature constant.

b. **Post-traumatic algor:**
   In which after a trauma (operation, injury, .. etc) the tissue is less perfused. simple explanation of this would be that the post-traumatic inflammation and remodeling
processes in the tissue mechanically or by reflex mechanism lead to a permanent reduction of tissue perfusion, in a way like a "micro-scar". From a Western point of view the microvascular responses to surgery, are likely to be involved in post-traumatic algor symptoms after any surgical intervention. This type of Algor would be the explanation for the post-operative pain in our study.

c. Immunological algor:
comprises regional reductions in MC due to vasoconstriction as part of an immunological response to an invading aggressor, a virus or bacterium.

d. Depletive algor:
comes from a lack of xue. If the warming fluid and nutrient of the body, or xue, is deficient some regions, especially the extremities, muscles, connective tissue and the conduits, may be less perfused, because xue flow is centralized to the body center, maintaining its flow in the intima (organs). Xue can be deficient for example due to loss of blood, i.e. after surgery or in women with hypermenorrhea. Lack of xue also occurs in cases of insufficient function of the stomachal and lienal orb, such as malabsorption, anorexia, chronic inflammatory bowel disease, cachexia due to consuming diseases (cancer, chronic inflammations). During lifetime, according to TCM theory, people tend to develop increasing xue deficiency. That is why elderly people tend to show symptoms of depletive algor. It is for this reason that the elderly are often heavily dressed, with long underwear even in the summer. When a doctor observes such behavior should think about the algor when the patient undresses. Obviously he/she need, unconsciously, to warm the conduits.

e. Toxic Algor:
Local toxic damage following extremely cold substances such as; voltarene, endoxan, alcohol.. etc

5. **Algor Laedens Theory** *(Shang Han Lun) as a diagnostic system for immuno-vegetative mechanism* *(3rd GC) – ALT : 6 stages model [42]*

In a Western understanding, the internal agents such as algor produce unbalanced reflex patterns and the body responds to these standards by counter-reactions. In Chinese medicine, this counter-reaction is called reactive Calor that can, according to Western medicine, even comprehend inflammation, increased microcirculation and sepsis. In the case of entering algor:
• A lack of regional microcirculation may be caused by defensive reflexes to cold, virus (adhesion molecules, complement system, coagulation).
• The counter-reaction is a general increase in microcirculation that is itself a regulatory process.

The specific signs of each stage, are due to conflicts of functional powers, with the agent algor, producing their symptoms. When the agent attacks the skin, there is a reduction of the defensive qi, like all other powers of the functional body. The algor in Western terms, translates into a lack of circulation, or decreased MC and affects primarily the conduit that contains more xue than qi.

The six energy layers comprise six different forms of energy which is technically:

I) Defensive qi (also referred to as Wei Qi), which resides within the extima outside the pipe and creates a first defensive barrier against external attacks;

II) Qi in the conduit, which is the qi within the conduits cardinal, since the main channels are the "conduits cardinal." When an agent blocks the flow of Qi that primarily will result in pain and functional disorders secondary of its orb. At this stage algor proceeds their invasion, causing blockages of qi, and therefore the onset of pain. At this point the body activates the xue, creating heat in the interior, to expel the algor drivers. It is in this stage that the algor is relates to pain, and calor is more reactive. If there is little reactive calor, there is an invasion of algor.

III) Xue in the conduit, that is guided by the Qi in the conduits and heat the conduits, while "nurture" and "moisten" the tissues. The heating effect in tissue is necessary to drive out the agent algor;

IV) Body Island qi, which is the qi in the intima, a general name for the entire interior of the body, where the functions of the orbs are generated in their respective parts of the body "islands" ("which are named according to the organs that lie approximately the same region);

V) Island xue body, which is a substantial part (yin) of the islands with body heat, thus activating and enhancing functional properties;

VI) Yin, which is the functional tissue, in the western subpopulation of cells, the substrate from which the functions (yang) develop.
According to the functional analysis, the invasion of Algor (fig. 6) is the postulate of uniform within the considerations made in six phases systematic defense of Chinese medicine. The Algor is an agent Yin with functional properties of deprivation.

Algor-induced signals and signs of orbs involved, and they are categorized into 6 stages of clinical signs.

I) Yang major, when the agent invades the skin, “attacks” the defensive Qi (Wei qi). The defensive qi does not remain in the conduits but in the skin surrounding the conduits and in all other tissues. Symptoms of Wei Qi are varied, but the symptom clinically decisive, may be the symptom of a general feeling of chills. The Orbs that are affect are the Vesical conduit and The Tenointestinal.

II) Splendor Yang, when the agent Algor enters the conduits, this leads to a regional block of the flow of qi and Xue. The flow of qi is blocked more easily than the flow of Xue as it’s the qi that moves the Xue. It is for this reason that the phases and the orbs are more prone to this problem if they depend more on qi. In this stage the affect Orbs are the Stomachal and the Crassintestinal.

III) Minor Yang, the Qi and Xue derive form the interior and are carried through the conduits system. If the agent Algor dominate the flow of Xue in the conduit, this may lead to a reverse flow Xue to the interior. The Algor also reaches the inside causing a feeling of internal cold.
Often the inside Xue (yin) will be mobilized against the agent causing the sensation of internal heat again, or if the agent Algor is expelled out, even heat temporarily abroad, i.e. the skin (extima). Literally, it says that the agent and flow of Xue within the conduit represent the “Tom and Jerry” expelling each other repeatedly. Here we have the affection of the Felleal and Tricalorical Orbs.

IV) **Yin major**, from this stage forward, the main symptoms don’t come from the conduits, but more frequently from the interior, the “body island” and it respective functions. When an agent affect the qi of the “body island”, the Lienal and the Pulmonary Orbs are the most affect, because the center and the metal are sensitives to the decrease of the activity of qi.

V) **Yin flectens**, when the Algor affects Xue in the inside, the functions of the Orbs of which depend on Xue are more easily affected than others. Since the Hepatic Orb is considered the Mare Xue (“sea of blood”), the functions of the Hepatic Orb may be weakened. Signs may also appear with symptoms such as from the Pericardial orb.

VI) **Yin minor**, the Yin is the structural condition to the yang development. Consequently, also the yin (functional tissue) is a technical form of energy. When this energy is affected by Algor, renal symptoms are more likely. Since the Yang results from the Yin, a similar process is the development of the ascendent Yang Qi that is in connection with the Cardial Qi. This connection is also expressed in terms of a Reno-Cardial axis, in which the pole yin is the Renal Orb and the pole Yang is the Cardial Orb.

6. **The significance of Algor as a pathogenic factor in this clinical scenario**

According to the HD model of TCM patients with pain after surgery are likely to be affected by post-traumatic algor which leads to local pain and decreased muscular strength, resulting in general pain.. Elderly patients are more likely in addition to developing depletive algor due to the age-related extent of xue-stasis due to surgery-associated factors. Therefore, we chose the leopard-spot technique.

Post-traumatic algor is induced by tissue trauma due to the initial injury and the surgical intervention which will result to a reduce of the microcirculation The relevancy of algor as a pathogenic factor in this clinical scenario automatically implies the application of the ALT as the 3°GC. There are several signs that indicate the presence of Stage I ( Yang major ) such as pain in the course of the vesical conduit. In this stage the agent affect Qi deffensivum ( wei Qi)
which is in the Extima, thus will result to a deactivation of Xue locally, according to Heidelberg model we can explain this by a lack of micro circulation. Clinically this will manifest with a cold skin and tearing pain.

The Vesical conduit is responsible of the Xue distribution in the body, its affection will results symptoms such as; cold feet; cold limbs; sciatic pain; low back pain; pain between the shoulder joints; stiff neck;, pain in the course of the conduit; feeling of tearing or pressure between the eyes. There is a general tendency not to retain by the vesical orb and the urine can not be " held " as normal, causing frequent light color urination.

The small intestine orb (It) is also affected at this stage, because of its relationship to the cardiac Yang orb (the latter responsible for the mobilization of the " Xue ") But also because of its connection with the vesical orb in stage I of ALT, causing symptoms such as pain in the shoulder, in the scapula, stiff neck and ear pain. There may be internal functional disorders of Tenintestinal such as mild diarrhea, discomfort or even moderate pain in the area below the navel.
1. Study Design

The study was designed as a prospective, controlled, single blinded clinical trial and was carried out according to the guidelines specified in the Declaration of Helsinki 2008 [43]. The ethical committee endorsed the study protocol prior to patient acquisition and informed consent was obtained from every patient.

2. Research Team

2.1 Main Investigator:
Fatine Hamza
- General Physician graduated from Faculty of Medicine and Pharmacy of University Cadi Ayyad in Marrakech – Morocco.
- Master student of Traditional Chinese Medicine at the Instituto de Ciências Biomédicas Abel Salazar (ICBAS).

2.2 Research Supervisors

2.2.1 Main Supervisor:
Professor Dr. Henry Johannes Greten
- Head of the Heidelberg School of Traditional Chinese Medicine
- President of the German Society of Traditional Chinese Medicine (DGTCM) Heidelberg-Germany
- Invited Associated Professor; Director of the Specialization and Master Program in Traditional Chinese Medicine; Department of Aquatic Production; Abel Salazar Institute for Biomedical Sciences, University of Porto, Portugal

2.2.2 Co-Supervisors:
Professor Manuel Laranjeira Gomes
- Neurosurgeon
- Director of Instituto de Neurociências
- Professor of Neurophysiology in ICBAS

Ana Alexandra Anjos
- Physiotherapist
- Teacher at TCM Master Program ICBAS/UP
• PHD student of Traditional Chinese Medicine at Abel Salazar Institute for Biomedical Sciences ICBAS

2.3 **Statistical Analysis**:
Statistical Analysis were conducted by Bruno Ramos from Fisiologia Aplicada Department in ICBAS.

3. **Study Objectives**:

3.1 **General Objective**:
- To evaluate the therapeutic effect of acupuncture in relieving post-operative pain.

3.2 **Specific Objectives**:
- To develop a clinical protocol for the treatment of post-operative pain after lumbar surgery
- To create a study design for the objective assessment of acupuncture effects in this condition

4. **Study Protocol**:

4.1 **Setting & Recruitment**
This Study was conducted in Casa De Saude Da Boavista, in Porto. Patients were recruited according to the defined inclusion and exclusion criteria – to be mentioned after a physical examination and medical history review.

4.2 **Ethics Assessment**:
The Study protocol was approved by the Ethical Committee of ICBAS [see annex 1].

4.3 **Informed Consent**:
Before patient enrollment the study staff explained the consent process in a detailed way. All patients were informed about the used technique of acupuncture, type of needles and the possible risks and secondary effects of acupuncture treatment [see annex2].

4.4 **Study Population**:
We recruited all patients who were operated in the lumbar spine for disc herniation or lumbar canal stenosis.
4.5 Eligibility Criteria

4.5.1 General Aspects:
Eligibility criteria were developed with the goal of maximizing enrollment at the local clinical setting. At the same time they served to establish a homogenous group of patients.

4.5.2 Inclusion Criteria:
- Patients between 20-80 years old
- Operated for Lumbar disc herniation Or Lumbar canal stenosis
- Operated by the Same Surgeon

4.5.3 Exclusion Criteria:
- Bleeding disorder
- Needle panic/fear
- Poor compliance to the study

4.6 Study Design
The study is single blinded, randomized, prospective and controlled.

4.6.1 Blinding:
- The Patients are blinded to the acupuncture since they can not distinguish between true and sham acupoints during the needling.
- The Acupuncturist is not blinded. A trained acupuncturist is doing the acupuncture and evaluate the pain and movement as it will be detailed.

4.6.2 Randomization:
Coin flip will divide the patients in to the verum “true” and sham “control” acupuncture groups. Patient's documentation sheet is marked with different colors according to which group they belong to.

4.6.3 Control:
The study control will be done using acupoints outside the conduits.

4.6.4 Acupuncture Intervention
a. General Description
The acupuncture treatment consisted in acupuncture with the technique "Leopard spot" on the chosen points: V40, R10, L6. During acupuncture intervention subjects rested in a prone position. Acupuncture was performed using a standard insulin syringe.
b. **Verum Acupuncture**

The verum Acupuncture consists on needling following the leopard spot technique on V40, R10, L6

---

**Table 3: Acupoints locations and areas of innervation. D – Dermatome, M – myotome, S – sclerotome, n/a not applicable**

<table>
<thead>
<tr>
<th>Point</th>
<th>Latin Name</th>
<th>Chinese Name</th>
<th>Position Description</th>
<th>Effect Description</th>
<th>Dermatome</th>
</tr>
</thead>
<tbody>
<tr>
<td>V40 / BL40</td>
<td>Medium Lacunae</td>
<td>Weizhong</td>
<td>In the middle of the popliteal fossa</td>
<td>Master point of the back, the conjunctory of the vesical conduit</td>
<td>D: S1/S2, M: S1/S2, S: n/a</td>
</tr>
<tr>
<td>R10/KI10</td>
<td>Vallis yin</td>
<td>Yingu</td>
<td>At the medial border of the popliteal fossa between the tendons of the semitendinosus and semimembranosus muscles</td>
<td>Conjunctory of the renal cardinal, tonifies the kidney yin and drains dump heat</td>
<td>D: L2/L3, M: S:</td>
</tr>
<tr>
<td>L6 / Sp6</td>
<td>Copulatio trium yin</td>
<td>Sanyinjiao</td>
<td>3 cun vertically above the malleolus internus at the posterior margin of the tibia</td>
<td>Master point of the lower caloric, all yin conduits of the foot merge there</td>
<td>D: L4/S1/S2, M: S1/S2, S: L4/L5</td>
</tr>
</tbody>
</table>

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**Table 4: Location of Verum Points [34]**

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c. **Sham Acupuncture**: 

The False “sham” acupuncture consists of needling following the leopard spot technique in non-acupoints in the following points:

- **Point one**: 4 Cun under the knee, then three fingers to the right.
- **Point two**: 8 cun up from the knee, then 2 fingers to the right.
- **Point three**: 8 cun up from the knee, then 2 fingers to the left.

The leopard spot technique consists of 5 rapid in-and-out bloodletting strokes with insulin syringe over the point’s skin area.

4.6.5 **Main parameters**:

a. **Subjective Pain assessment**:
Patient in supine position asked to move his leg up from the bed in total knee extension to the maximum point he/she can and via Visual Analog Scale (VAS) for pain (fig 13) Patient is asked to indicate the pain between 0 (no pain) to (10 maximum pain). The pain evaluation is made twice T0 before puncture and T1 after acupuncture.

![Figure 10 Visual Analog Scale – © scielo.br](image)

b. **Objective pain assessment:** measuring the angle of the hip in the straight leg raise test (modified Lasegue Test) to the painful point of the active movement (figure 14) with a goniometer (figure 15) in T0 before acupuncture and in T1 after acupuncture. The VAS is evaluated at the same moment of the measuring.

![Figure 11: Lasegue test - © wikihow](image)

![Figure 12: Goniometer © Fatine Hamza Photography](image)
c. **Data to be analyzed:**

- VAS before and after the acupuncture. T0 and T1.
- Angle measurement by goniometer before and after acupuncture in T0 and T1
- comparison between the verum acupuncture group and the sham acupuncture group
- comparison within the same group (verum and sham).

d. **Study Illustration:**

![Study Illustration Diagram]

Intervention phase: verum OR sham acupuncture

T0 = measurement of the hip angle in lasgue test + VAS evaluation

T1 = re-measurement of the hip angle in lasgue test + VAS re-evaluation


e. **Study chronology:**

<table>
<thead>
<tr>
<th>Time period</th>
<th>Time period</th>
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<tr>
<td><strong>December 2013 – March 2014</strong></td>
<td>Literature research; preparation of the research protocol.</td>
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<tr>
<td><strong>April 2014</strong></td>
<td>Submission of the research project to ICBAS for Ethics Committee assessment (see approval Annex 1).</td>
</tr>
<tr>
<td><strong>May 2014 – March 2015</strong></td>
<td>Patient selection according to the inclusion criteria of this study, and data recruitment. Study protocol practical work and continuous patient recruitment and enrolments.</td>
</tr>
<tr>
<td><strong>April - May 2015</strong></td>
<td>Data Analysis, Master thesis writing corrections</td>
</tr>
<tr>
<td><strong>June 2015</strong></td>
<td></td>
</tr>
</tbody>
</table>
f. *Statistical Analysis*:  
The data collected were processed using the following statistical analysis software: Microsoft Excel 2010 and IBM SPSS Statistics 22. The Microsoft Excel 2010 program, was used to calculate the descriptive measurements, mean and standard deviations of the sample characteristics. the IBM SPSS Statistics 22 program was used to perform inductive analysis of the data.

g. *Research partnership*:  
Cooperation between ICBAS TCM Master Program and casa de saude da Boavista was established. Agreement for the research project was obtained from the Ethical Committee in ICBAS.
Chapter III
Results
The purpose of this study was to analyze the immediate acupuncture effect on post-operative pain and to answer the following questions:

Does acupuncture has an immediate effective on Post-operative pain?
Is there is a difference between true acupuncture and Sham acupuncture?

Our results were as following:

A. Socio-demographic characteristics:

Data were obtained from 30 patients; 15 in the intervention group and 15 in the control group. All patients were seen 24h after Lumbar spine surgery.
The Median age of our group was 54.7. with a maximum of 79 and a minimum of 32 years.
The gender distribution was as following: 12 females and 18 male.

<table>
<thead>
<tr>
<th>socio-demographic characteristic</th>
<th>Overall sample</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Age</td>
<td>54.7</td>
<td>53.2</td>
<td>56.3</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>18</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>12</td>
<td>5</td>
</tr>
</tbody>
</table>

B. Operative Indications:

All our patients were operated for one of two indications: Lumbar Disc Disease (LDD) and Lumbar Spinal Stenosis (LSS). The two groups had equal number of patients for each indication.
C. Angle Measurement:

Before starting the acupuncture we ask the patient to evaluate his pain on the VAS scale and we measure the hip angle in a modified Lasegue Test in the most painful leg – see last chapter for details – such measurement allows us to evaluate objectively the acupuncture effect. As can be seen from graph 2 the angle degree increased significantly among both groups.
D. Verbal Analogic Scale : VAS

As a subjective way, we evaluate the VAS before and after acupuncture over a scale of 10 mm. The VAS decreased by almost half in both groups.

![Graph 3: Pain Before Vs. After](image)

Graph 3: Pain Before Vs. After

We remark a significant difference in Mobility and pain before and after acupuncture in true acupuncture and sham acupuncture.

E. Difference between the two groups:

By comparing data from both groups we found out that the percentage of improvement in VAS is higher in true acupuncture than in Sham (Graph 4). However, this difference is not significant.
The mobility improvement was more important in verum group than in sham group. This difference was not statistically significant $P > 0.005$.

Graph 4: Improvement in VAS between groups

Graph 5: Evolution in Angle measurement between groups
To summarize: There are no significant differences between true acupuncture and sham acupuncture groups at the end. However, there is a significant difference within each group before and after the acupuncture. A low case number is the most probable cause of not being significant. To achieve a significant difference we need to recruit 83 patients. This Number was calculated via a size effect formula according to professor Helio Amante Miot [72].
Chapter IV
Discussion
A. Distinctive features of the study design:

Many studies and researches focused on the analgesic effect of acupuncture that was proved to be existed. However, the specificity of that effect was largely debated between researchers. Therefore, in this study, it was sought to examine what is the immediate effect of acupuncture on post-operative pain. Our clinical trial was designed as a prospective, controlled, single blinded study to answer the two basic questions:

1- Does acupuncture has an immediate effect on post-operative pain?
2- Is there a difference between verum acupuncture group and sham acupuncture group?

Before discussing our results we will discuss the study design that we followed. Starting by the choice of acupoints: we chose three points during the whole study, all three are in the lower burner of the body and from the Lienal (Spleen), Renal (Kidney) and Vesical (Bladder) conduits.

Medium Lacuna, Weizhong or V40 (BL40) was chosen because of its priorities in back pain as the master point of the back [32]. This point has an effect on the Dermatomes S1 and S2 [44]. Vallis yin, Yingu or R10 (KI10) is the conjunctury point, tonifies the kidney yin and drains dump heat. The dermatomes in question are L2,L3 finally, Copulatio trium yin, Sanyinjiao or L6 (SP6) is the Master point of the Lower burner and also the Point where the three yin conduits join [32]. This point has an effect on the dermatomes L4,S1 and S2.

The choice of sham acupoints was focusing on having points outside of the conduits paths however, we intentionally chose points which have common dermatomes with the verum points in order to evaluate the specific segmental effect. Our points has an influence on the dermatomes: L5, L2 and S2. This choice was motivated by our well to examine the specific segmental effect of acupuncture.

To measure the pain improvement we chose two simple methods:

- Subjective: by using the VAS before and after acupuncture. The VAS is a simple and often used method for evaluating variation in pain intensity. Its use was approved by several studies for the evaluation of post-operative pain such as Bodian & Freedman [45] and Deloach LJ, Higgins before them [46]. However, Lauran J [47] mentioned
some limitations for the VAS in the immediate post-operative pain therefore we opted to join another evaluation method.

Objective: by measuring the angle of the hip in the straight leg raise test (modified Lasegue Test) to the painful point of the active movement before and after the acupuncture. This measurement is done using a Goniometer. Many researchers proved the validity and the reliability of manual goniometers for measuring the hip range of movements [48] [49]. The improvement of the movement will allow us to evaluate indirectly the evolution of the pain.

It is important to mention that all our patients received a conventional treatment for post-operative pain consisted of: Paracetamol 1g three times a day and Cox-inhibitor once a day. This treatment was not modified during our study for ethical reasons.

B. socio-demographic characteristics:

Regarding the characterization of the sample, we found a ratio male/female of 1.5. Other studies found a masculine predominance in LDD by a higher ratio [50][51]. The sex ratio registered in LSS studies showed a feminine predominance [52][53] however our sample had more LDD than LSS – see chapter results-. Our Median age was 54.7 which is less than the median age mentioned in other studies [53][51].

C. Verum Group:

Our verum group showed a significant improvement in the measurement of the hip angle in extension after acupuncture. This results went together with the VAS numbers which presented a significant decrease in the level of the pain immediately after acupuncture. This decrease reached almost half of the initial pain level. Our results confirmed that acupuncture can be used as a post-operative pain analgesic, it also proved the efficiency of the points choice. Acupuncture analgesic effect is not new thing to discover, it is well known and studied in literature and explained by many mechanisms - see chapter introduction. A systematic review of randomized controlled trials was done in 2008 in USA [54] studied the acupuncture effect for post-operative pain by including various type of operations and various technics of acupuncture. The outcome of this meta-analysis found that acupuncture and related techniques are effective adjuncts for post-operative pain management as demonstrated in the study by a significant reduction.
of post-operative pain scores and opioid consumption [54]. Other researches focused on different surgical interventions such as Langenbach [41] who studied the acupuncture effect post-haemorrhoidectomy and stated that acupuncture appears to be an effective adjunct to conventional analgesia.

Richard Rong Wan, 2000, did a similar study to ours in Germany but he included only LDD patients and the sample was extremely larger (132 patients) in their study, the results stated that classical acupuncture resulted a significant reduction in pain that become increasingly stronger during the 6h study period [55].

The acupuncture technique we chose – Leopard spot – is not very well explored in scientific research, although it is one of the oldest and known to have a significant effect [56]. This technique is characterized by multiple points of bleeding which looks like leopard markings. To select one acupoint as the center and to needle sparsely around for blood-letting [57]. Most scientific researches in acupuncture field are done by classical acupuncture techniques, we aimed to choose the leopard spot technique because of its value in the movement of qi and xue and removing the agents. Pain is mostly defined by a stagnation of xue and/or a blockage of qi [42] therefore Leopard spot technique is ideal for this purpose. Lingshu [58] states in his text about the leopard spot technique: "This can be used to drain fevers, to draw blood, and to exhaust chronic diseases."

Bleeding is recommended because it can drain the excess, alleviate congestion and stasis, and remove the pathogens. As described in Fundamentals of Chinese Acupuncture [59], the function of blood-letting therapy is "to drain heat or quicken the blood and qi and relieve local congestion."

D. Sham Group:

As can be seen from figures in chapter two, our results in control group were not different from the intervention group. The Angle measurement increased significantly after. As for the VAS, we had as well a significant decrease after acupuncture which was compatible with the angle measurement.

Our results were not unusual, many researchers reported an effect in the control group. This effect can be explained by several theories:
In our study we used the leopard spot technique that has a systemic effect on the qi and xue of the body.

Our sham points had common dermatomes with the true acupoints, knowing that acupuncture has a segmental effect [60] this explains the effect of the sham points.

Wang [55] stated that sham acupuncture lead to same early pain relief that did not reach statistic significant and then declined thereafter. in our Study we evaluated only the immediate effect of acupuncture therefore, a further pain assessment might be necessary to evaluate the sham acupuncture effect.

The theory of absence of a specific effect of acupuncture must be argued as well as one of the possible explanations for our results in this group.

Different studies suggest different techniques for the control acupoints, such as: superficial needling by Wang [55], electro stimulation at non acupoints by Chiu HJ [61], needle touch without penetration at non acupoint by Sim [62], or even Plastic tubes taped at non acupoints as Leo did [63]. In our study we used the same technique for both groups.

Sham acupuncture was initially assumed to be ineffective by most investigators and therefore ideal as a placebo. However, Lewith and Machin[64] showed that sham acupuncture appeared to have an analgesic effect in 40% to 50% of patients compared with 60% to 75% for real acupuncture. There is evidence that acupuncture at non-classical locations may have analgesic effect [65]. It is also very likely that such effect could be endorphin mediated [62], therefore requiring a very large sample size to detect a difference between real acupuncture and sham acupuncture.

Five large German trials all found relatively large effect of sham acupuncture over no-treatment group [66,67,68,69,70] These German trials have comparably high quality but if they are excluded differences between sham acupuncture and other physical placebo are no longer significant[71]. Therefore further trials are required to investigate these facts.

**E. Limitations and suggestions:**

The prime limitation for this study is the reduced number of our sample. Other studies with larger number might have more reliable results specially concerning the effect of
sham accupoints. A low case number is the most probable cause of not being significant. To achieve a significant difference we need to recruit 83 patients.

We were limited by a one-time evaluation immediately after the acupuncture. Further evaluations by VAS and angle measurement were not possible in our case, however they might be suggested for future research.

Another suggestion for future research would be to have a double blind trial which was not the case in our study. Double blinding can minimize any possible placebo effects inherent to the acupuncture technique used.

F. Impact of the findings on future acupuncture trails:

Our study protocol provides evidence that acupuncture treatment, according to Heidelberg model of TCM, can result in improvements in post-operative pain after lumbar surgery.

Our research shed the light as well on the leopard-spot technique in the pain treatment. A technique that is well known but not often used neither explored by researchers. Moreover, we explored the functionality of the master points as a choice for pain treatment. And Finally, we added more doubts to the validity of sham acupuncture as a placebo treatment in scientific protocols.
Chapter V
Conclusion
Acupuncture showed to be an effective way of treatment in post-operative pain after lumbar surgery for LDD and LSS. No side effects for acupuncture were found in our study. A significant difference was found before and after the acupuncture in patients who were consuming their conventional analgesic medication. The Subjective and Objective methods of measurements were both improved after acupuncture. A difference was found between verum and sham groups, however, it was not statistically significant. We encourage having future trials with a larger number of patients to evaluate this difference. Finally, acupuncture can be used effectively as an adjunct to conventional analgesia in surgery departments.
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<table>
<thead>
<tr>
<th>Author</th>
<th>Year of Publication</th>
<th>Title</th>
<th>Study type</th>
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<td>Young-Hun Cho Ms</td>
<td>2014</td>
<td>Acupuncture for acute postoperative pain after back surgery</td>
<td>Meta-analysis of randomized controlled trials</td>
<td>The meta analysis showed positive results for acupuncture treatment of pain after surgery in term of VAS for pain intensity 24 h after surgery when compared to sham acupuncture</td>
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<td>Carlo Ammendolia</td>
<td>2014</td>
<td>Degenerative lumbar spinal stenosis and its imposter</td>
<td>Three case studies</td>
<td>The purpose of this study is to highlight the diagnostic challenges using three case studies.</td>
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<td>Stephen Kishner</td>
<td>2010</td>
<td>Electrodiagnosis in lumbar spinal stenosis</td>
<td>Review</td>
<td>Electrodiagnosis studies show dynamic physiological neural function and has become a valuable tool in LSS</td>
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<td>Roger Chou</td>
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<td>Diagnosis and treatment of low back pain</td>
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<td>Need for improved treatment of postoperative pain</td>
<td>A cross-sectional study</td>
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<td>B. Milakovic</td>
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<td>Strategies for post operative pain relief in neurosurgical intensive care unit</td>
<td>Review</td>
<td>The pain management regimen must be individualized on the basis of patient response which is influenced by variables.</td>
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<td>Wilco C. H. Jacobs</td>
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<td>Surgery versus conservative management of sciatica due to a lumbar herniated disc</td>
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<td>There is evidence that early surgery in patients with sciatica provides for a better short term relief of leg pain as compared to prolonged conservative care</td>
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<td>Authors</td>
<td>Year</td>
<td>Title</td>
<td>Type</td>
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<tr>
<td>Zhi-Qi Zhiao</td>
<td>2008</td>
<td>Neural Mechanism underlying acupuncture analgesia</td>
<td>Review</td>
<td>Acupuncture analgesia is essentially a manifestation of integrative processes at different levels of the CNS between afferent impulses from the pain region and impulses from the acupoints</td>
</tr>
<tr>
<td>John Nguyen</td>
<td>1999</td>
<td>Pour une evaluation confidante et determine de l'acupuncture</td>
<td>Medicale</td>
<td>Il s’agit simplement de permettre à chacun de situer sa pratique par rapport à celle de ses pairs et par rapport aux faits observés</td>
</tr>
<tr>
<td>Jean Marc Stephan</td>
<td>2007</td>
<td>Acupuncture, receptrice transmembranaires à tyrosine- kinases à cytokines et transduction</td>
<td>Animal experiment</td>
<td>La transduction est est l’une des clefs du mécanisme d’action de l’acupuncture.</td>
</tr>
<tr>
<td>Jaung-Geng Lin</td>
<td>2008</td>
<td>Acupuncture Analgesia</td>
<td>Review of mechanisms of Actions</td>
<td>Many researchers have tried to investigate whether there is a specific pathway involved in AA.</td>
</tr>
<tr>
<td>Klaus Linde</td>
<td>2010</td>
<td>Are sham Acupuncture interventions more effective than placebos</td>
<td>Re analysis of data from the Cochrane review on placebo effect</td>
<td>Due to the heterogeneity of the trails included and the indirect comparison our results must be interpreted with caution still sham acupuncture might be associated with larger effect than pharmacological effect</td>
</tr>
<tr>
<td>Young Dal Kwon</td>
<td>2007</td>
<td>Systematic review of cupping including bloodletting therapy for musculoskeletal diseases in korea</td>
<td>Systematic review</td>
<td>The evidence for the effectiveness of bloodletting plus acupuncture for treating patients with low back pain was effective.</td>
</tr>
<tr>
<td>P. Prithvi Raj</td>
<td>2008</td>
<td>Intervertebral Disc: Anatomy - Physiology – Pathophysiology – Treatment</td>
<td>Review</td>
<td>This reviews article describes anatomy, physiology, pathophysiology and treatment of intervertebral disc.</td>
</tr>
<tr>
<td>Author</td>
<td>Year</td>
<td>Title</td>
<td>Study Type</td>
<td>Summary</td>
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<tr>
<td>Mingdong Yun</td>
<td>2012</td>
<td>Hegu Acupuncture for Chronic Low back Pain</td>
<td>Randomized controlled trial</td>
<td>Hegu acupuncture is significantly more effective than standardized acupuncture especially in the long term</td>
</tr>
<tr>
<td>Seiji Ohtori</td>
<td>2012</td>
<td>Conservative and surgical treatment improves pain and ankle brachial index in patients with Lumbar Spinal Stenosis</td>
<td>Prospective randomized trial</td>
<td>Improvement of the spinal nerve roots by medication and decompression surgery may improve the supply of blood flow to the lower leg in patients with LSS</td>
</tr>
<tr>
<td>Christy C. Tomkins-lane</td>
<td>2013</td>
<td>Predictors of objectively measured walking capacity in people with degenerative lumbar spinal stenosis</td>
<td>Prospective randomized controlled</td>
<td>Factors found to be most highly associated with walking capacity in LSS were self-reported, pain-related function and presence of leg pain immediately following walking.</td>
</tr>
<tr>
<td>Johannes Weisse</td>
<td>2013</td>
<td>Effectiveness and Acceptance of Acupuncture in patients with Chronic low back pain</td>
<td>Prospective randomized controlled trial</td>
<td>Acupuncture was highly accepted and had positive effects in patients with chronic low back pain.</td>
</tr>
<tr>
<td>Y.Sun, T. J.</td>
<td>2008</td>
<td>Acupuncture and related techniques for postoperative pain</td>
<td>Meta-analysis review of randomized controlled trials</td>
<td>This systematic review suggest that the perioperative administration of acupuncture may be a useful adjunct for postoperative analgesia</td>
</tr>
<tr>
<td>Florian Beissner</td>
<td>2010</td>
<td>Investigation of Acupuncture sensation patterns under sensory deprivation using a geographic information system</td>
<td>Investigation</td>
<td>The study has proven to be a valuable tool to study propagated sensations along channels</td>
</tr>
<tr>
<td>Kotani N.</td>
<td>2001</td>
<td>Preoperative intradermal acupuncture reduces postoperative pain, nausea, and vomiting, analgesic requirement and sympathoadrenal</td>
<td>Controlled and double blind study</td>
<td>Preoperative intradermal acupuncture reduces postoperative pain the analgesic requirement and opioid related side affects after both upper and lower abdominal surgery</td>
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<tr>
<td>Chin – Keng sim</td>
<td>2002</td>
<td>Effect of</td>
<td>Randomized</td>
<td>Preoperative EA has a short</td>
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<tr>
<td>Author</td>
<td>Year</td>
<td>Title</td>
<td>Study Design</td>
<td>Key Findings</td>
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<tr>
<td>Joshua Bauml</td>
<td>2013</td>
<td>Electroacupuncture on intraoperative and post operative analgesic requirement</td>
<td>Case report</td>
<td>Acupuncture was successfully used to treat a woman with severe and persistent PMPS</td>
</tr>
<tr>
<td>Max Karner</td>
<td>2013</td>
<td>Objectifying specific and nonspecific effects of acupuncture in osteoarthritis of the knee</td>
<td>Double-blinded randomized trial</td>
<td>Non-specific needling achieved about two third of the subjective pain relief achieved after classical acupuncture suggesting considerable non specific effect</td>
</tr>
<tr>
<td>M.R. Langenbach</td>
<td>2011</td>
<td>Acupuncture for postoperative pain control after stapled haemorrhoidopexy</td>
<td>Randomized sham-controlled trial</td>
<td>In haemorrhoidopexy patients, acupuncture appears to be effective adjunct to conventional analgesia</td>
</tr>
<tr>
<td>Y. Sun</td>
<td>2008</td>
<td>Acupuncture and related techniques for postoperative pain</td>
<td>Systematic review of randomized controlled trials</td>
<td>Postoperative administration of acupuncture may be a useful adjunct for postoperative analgesia</td>
</tr>
<tr>
<td>T I Usichenko</td>
<td>2013</td>
<td>Perioperative acupuncture: why are we not using it?</td>
<td>Meta-analysis of 15 randomized controlled trials</td>
<td>Good evidence for the effectiveness of perioperative acupuncture in the treatment of postoperative pain</td>
</tr>
<tr>
<td>Jaime Guzman</td>
<td>2001</td>
<td>Multidisciplinary rehabilitation for chronic low back pain</td>
<td>Systematic review</td>
<td>Provided evidences that intensive multidisciplinary bio psychosocial</td>
</tr>
<tr>
<td>Luke D Jones</td>
<td>2014</td>
<td>Back Pain In the Elderly</td>
<td>Review</td>
<td>Chronic LBP in older people should be considered a clinical syndrome with multiple physical contributors</td>
</tr>
<tr>
<td>Carol A Bodian</td>
<td>2001</td>
<td>The Visual Analog Scale for pain. Clinical significance in postoperative patients</td>
<td>Prospective randomized study</td>
<td>Grouping final VAS scores into a small number of categories provides greater clinical relevance for comparisons than using the full spectrum of measured values or changes in value</td>
</tr>
<tr>
<td>Silvio Nussbaumer</td>
<td>2010</td>
<td>Validity and test retest reliability of manual</td>
<td>Randomized prospective</td>
<td>Goniometer based assessments considerably</td>
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<tr>
<td>Goniometer for measuring passive hip range of motion in femoroacetabular impingement patients</td>
<td>Study</td>
<td>Overestimate hip joint ROM by measuring intersegmental angles rather than true hip ROM.</td>
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<tr>
<td>Lauren J. DeLoach</td>
<td>1997</td>
<td>The Visual Analog scale in the immediate postoperative period</td>
<td>Prospective randomized study</td>
<td>VAS correlates well with a verbal 11 points scale but that any individual determination has an imprecision of +/- 20 mm</td>
</tr>
<tr>
<td>Hyun-Jong Lee</td>
<td>2014</td>
<td>Acupuncture for low back pain due to spondylolisthesis</td>
<td>Randomized controlled pilot trial</td>
<td>Providing resources for incorporating acupuncture into existing pain management methods</td>
</tr>
<tr>
<td>Gregory Glazov</td>
<td>2013</td>
<td>Low dose laser acupuncture for non-specific chronic low back pain</td>
<td>Double blind randomized controlled trial</td>
<td>LA using energy density range 0-4j/cm² for the treatment of chronic non-specific LBP resulted in clinical improvement unrelated to laser simulation</td>
</tr>
<tr>
<td>N J Stomski</td>
<td>2013</td>
<td>The experience of acupuncture care from the perspective of people with chronic LBP</td>
<td>Qualitative study</td>
<td>Patients attested being more calm during the acupuncture sessions</td>
</tr>
<tr>
<td>Tatiana Molinas Hasegawa</td>
<td>2014</td>
<td>Acupuncture for acute non-specific LBP</td>
<td>Randomized controlled, double-blind placebo trial</td>
<td>Yamamoto’s new scalp acupuncture was more effective than sham treatment with regard to decrease in pain and anti-inflammatory intake as well as improving functional status and quality of life for patients with ANLBP</td>
</tr>
<tr>
<td>Hamidrezma Bahrami</td>
<td>2014</td>
<td>Acupuncture for Chronic Low back pain</td>
<td>Randomized controlled Trial</td>
<td>Accompanying routine acupuncture with time method acupuncture can enhance the efficacy of treatment and the persistence of its benefits in individuals with cLBP</td>
</tr>
<tr>
<td>Michael Haake</td>
<td>2007</td>
<td>German Acupuncture Trials for Chronic LBP</td>
<td>Double blinded randomized controlled trial</td>
<td>LBP improved after acupuncture treatment for at least 6 months</td>
</tr>
<tr>
<td>Mai Xu</td>
<td>2013</td>
<td>Acupuncture for chronic Low Back Pain</td>
<td>Meta-analysis of 13 randomized</td>
<td>Acupuncture has been reported to be effective in</td>
</tr>
<tr>
<td>Penny Taylor</td>
<td>2013</td>
<td>Cost-effectiveness of Acupuncture for chronic nonspecific LBP</td>
<td>Assessment</td>
<td>Assessment of cost effectiveness of acupuncture in alleviating chronic LBP either alone or together with standard care compared with patients receiving routine care and/or sham</td>
</tr>
</tbody>
</table>
Annexes
Annex 1: Ethical Committee Approval

PROJETO Nº 063/2014

Título: Acupuncture analgesia in post-operative pain in herniated lumbar disc surgery

Investigador Principal: Fatine Hamza
Outros Investigadores: Ana Alexandra Santos e Maria João Santos
Orientador: Henrey Greten
Coorientador: Manuel Laranjela
Duração do Projeto: 01 abril a 31 de agosto 2014 (Instituto de Neurociências)

A Comissão de Ética do ICBAS-UP reuniu dia 13 de fevereiro de 2015 no edifício do ICBAS
- Sala de reuniões do Departamento de Ciências do Comportamento, na presença de Liliana de Sousa, Manuel Vilar, Margarida Araújo, Maria Antónia Gonçalves e Paulo Maia. Decidiu emitir parecer favorável à realização do projeto supracitado, por unanimidade.

Solicitamos que envie anualmente a esta Comissão um resumo dos resultados obtidos na sequência deste projeto.

Com os melhores cumprimentos,

Pela Comissão de Ética do ICBAS-UP,

[Signature]

Prof. Doutora Liliana de Sousa (presidente)

To whom it may concern,

The above project is in accordance with the Portuguese law and the ICBAS-UP Ethics Committee criteria.
ANNEX 2: INFORMED CONSENT FOR PATIENTS

DECLARACÃO DE CONSENTIMENTO

Considerando a “Declaração de Helsínquia” da Associação Médica Mundial
(Helsínquia 1964; Tóquio 1975; Veneza 1983; Hong Kong 1989; Somerset West 1996 e Edimburgo 2000)

Designação do Estudo (em português):

Eu, abaixo assinado, (__________________________), declaro não ter participado em nenhum outro projecto de investigação durante este internamento, tendo compreendi do a explicação que me foi fornecida acerca do meu caso clínico e da investigação que se tencionava realizar. Foi-me ainda dada oportunidade de fazer as perguntes que julguei necessárias, e de todas obtive resposta satisfatória. Tomei conhecimento de que, de acordo com as recomendações da Declaração de Helsínquia, a informação ou explicação que me foi prestada versou os objectivos, os métodos, os benefícios previstos, os riscos potenciais e o eventual desconforto. Além disso, fui-me afirmado que tenho o direito de recusar a todo o tempo a minha participação no estudo, sem que isso possa ter como efeito qualquer prejuízo na assistência que me é prestada. Por isso, consinto que me seja aplicado o método, o tratamento ou o inquérito proposto pelo investigador.

Data: ___/___/2014
Assinatura do doente ou voluntário são: ____________

__________________________
O Investigador responsável:
Nome: Fatine Hamza
Assinatura: