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ORIGINAL ARTICLE

Chronic lumbar pain: rehabilitation

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DESCRIPTION OF THE EVIDENCE COLLECTION METHOD:

This study revised articles from the MEDLINE (PubMed) databases and other research sources, with no time limit. To do so, the search strategy adopted was based on (P.I.C.O.) structured questions (from the initials "Patient"; "Intervention"; "Control" and "Outcome". As keywords were used:

Question 1: low back pain AND (analgesics OR paracetamol OR acetaminophen OR dipyrone);

Question 2: (Chronic back pain OR chronic low back pain OR chronic lumbar pain OR back pain OR lumbar pain OR low back pain OR lumbago) AND (Anti-Inflammatory Agents, Non-Steroidal OR NSAIDs OR aspirin OR indomethacin OR diclofenac OR piroxicam OR tenoxicam OR meloxicam OR phenylbutazone OR ibuprofen OR naproxen OR nimesulide OR Cyclooxygenase 2 Inhibitors OR valdecoxib OR celecoxib OR etoricoxib);

Question 3: (Opioids or Narcotics or Morphine or Oxymorphone or Hydromorphone or Tapentadol or Morphine derivates or Oxycodone or Hydrocodone or Fentanyl or Tramadol or Codeine or Buprenorphine or Methadone or Dextropropoxyphene) and (low back pain or back pain or lumbar pain);

Question 4: (chronic back pain OR chronic low back pain OR chronic lumbar pain OR back pain OR lumbar pain OR low back pain) AND (antidepressant OR duloxetine OR venlafaxine OR amitriptyline OR nortriptyline OR clomipramine OR imipramine OR desvenlafaxine OR fluoxetine OR sertraline OR citalopram OR mirtazapine OR paroxetine OR tryciclic antidepressant OR dual antidepressant);

Question 5: low back pain AND (muscle relaxants OR cyclobenzaprine OR diazepam OR benzodiazepines OR carisoprodol OR tizanidine OR tetrazepam);

Question 6: Low Back Pain AND (Hyperthermia, Induced OR Diathermy OR ultrasonic therapy OR shortwave therapy OR ultrasound OR infrared rays OR microwaves);

Question 7: (Transcutaneous Electric Nerve Stimulation OR TENS) AND Low Back Pain;

Question 8: (physical exercise program OR exercise therapy OR muscle stretching exercises OR exercise movement techniques) AND (low back pain OR chronic low back pain);

Question 9: (acupuncture or electroacupuncture) AND (Low Back Pain OR "Lumbar Myofascial pain");

Question 10: Human Engineering AND Low Back Pain;

Question 11: Low Back Pain AND Exercise;

Question 12: ((low back pain or (lumbar and chronic pain)) and acupuncture and economics.

With the above keywords crossings were performed according to the proposed theme in each topic of the (P.I.C.O.) questions. After analyzing this material, therapy narrow articles regarding the questions were selected and, by studying those, the evidences that fundamented the directives of this document were established.

LEVEL OF RECOMMENDATION AND EVIDENCE:

A: Strong consistency experimental or observational studies.

B: Fair consistency experimental or observational studies.

C: Case reports (uncontrolled studies).

D: Opinion lacking critical evaluation, based on consensus, physiological studies or animal models.

OBJECTIVES:

Offering information about the treatment of chronic non-specific lumbar pain.

PROCEDURES

Therapeutic for chronic non-specific lumbar pain.

CONFLICTS OF INTERESTS:

There are no declared conflicts of interests.

INTRODUCTION

Pain in the lumbar spine is the concept of the term lumbar pain. This is a disorder that afflicts both genders, ranging from sudden pain to intense and sustained pain, generally short in duration. The combinations based in the patients symptoms and additional tests are the criteria used to classify lumbar pain types. Thus, those can be categorized with a certain degree of specificity in the prognosis[1] **(A)**.

There are two types of lumbar pain, specific and non-specific[2] **(A)**.

When there is a determined cause, they are called specific. For these we can mention the intrinsic causes such as congenital, degenerative, inflammatory, infectious, tumoral, and mechanic-postural conditions, and, as extrinsic causes, the imbalance between functional load, the effort required in work and activities of daily life. In addition to those, there are postural stress and acute lesions that cause structural deterioration[2] **(A)**.

When no justification is found for the cause, it is called idiopathic or non-specific lumbar pain[2] **(A)**.

The recommendations in this document are intended for patients with chronic non-specific lumbar pain, being considered chronic a continuous, long-term pain of more than 12 weeks[2] **(A)**.

It is not recommended to patients with history of prolapse of one or more spinal discs with concurring neurological symptoms; patients submitted to spinal surgery; infectious spondylitis; inflammation-related lumbar pain; malignant or autoimmune disorders; congenital malformations of the spine, with the exception of lordosis or scoliosis; compression fracture caused by osteoporosis; spinal stenosis; and spondylolysis or spondylolisthesis[2] **(A)**.

Nowadays, one cannot think about rehabilitation methods without tying the available interventions for lumbar pain to economical assessments. Thinking about these aspects, the evidence-based directive allows helping the physicians and government officials to identify the most beneficial and cost-effective treatments, avoiding both financial and time losses to patients[3] **(A)**.

1. What is the benefit of regular analgesics in the control of chronic non-specific lumbar pain and for how long can those be used?

The use of acetaminophen, in 1000 mg dose, four times a day, orally administered, during four weeks, is inferior to 500 mg of sodium salicylate in two doses a day in the reduction of pain and disability of patients with chronic lumbar pain of more than six months duration and with no associated neurological symptoms[4] **(A)**.

Acetaminophen, in 325 mg dose, in combination with tramadol, in 37.5 mg dose, orally administered, four times a day, during ninety-one consecutive days, improves chronic lumbar pain with absolute risk reduction in 88.4% (CI 95% 78% to 99%) and benefits one out of each nine patients treated (NNT = 9, CI 95% 5 to 101). The adverse events reported in the treated group include nausea (13%), speepiness (12.4%) and constipation (11.2%). One in each eight patients presented adverse effects (NNH = 8, CI 95% 5 to 17)[5,6] **(A)**.

There are evidences, with use of less than four grams, of severe drug-induced hepatitis as adverse effect[5] **(A)**.

Recommendation

Acetaminophen (paracetamol), in 500 mg dose four to six times a day, orally administered, during four weeks is recommended for patients with chronic non-specific lumbar pain[4] **(A)**.

2. What is the benefit of NSAIDs non steroidal anti-inflammatories in the treatment of chronic non specific lumbar pain?

Non-steroidal anti-inflammatories (NSAIDs) are used due to their antipyretic, analgesic, and anti-inflammatory effects. NSAIDs can inhibit the Cyclooxygenase enzyme (COX), which can be presented in at least two isoforms:COX-1 and COX-2, being classified according to their ability of inhibiting either one or the other isoform. The most recent NSAIDs are predominantly selective inhibitors of COX-2, whereas the older ones are less selective inhibitors[4] **(A)**.

Non-selective COX inhibitors

The use of indomethacin, 25 mg, three times a day for six weeks, is similar to the use of piroxicam in 20 mg daily dose in the treatment of chronic lumbar pain, showing improvement in the ability to perform tasks, mobility and pain reduction. The most common adverse effects reported are gastrointestinal irritation and fatigue, diarrhoea, cardiovascular risk, constipation, and tongue pain in the treatment with piroxicam[7] **(A)**.Piroxicam beta cyclodextrin in 20 mg daily dose shows to be more effective than piroxicam in the same dose, showing average variation in the Visual Analogue Scale (VAS, 0 to 100 mm) of 3.07 ± 1.56 compared to 1.75 ± 1.48 in twenty-eight days of treatment[8] **(A)**.

Diclofenac in 150 mg daily dose for four weeks is effective in pain reduction and improvement of physical ability in patients with chronic lumbar pain[9] **(A)**.

Naproxen, 550 mg, twice a day, for fourteen days is effective in the general reduction of pain, alleviating also night pain and the pain caused by movement in patients with chronic lumbar pain. Diflunisal, 50 mg, twice a day, for fourteen days, does not show significant differences compared to the placebo. Naproxen is superior compared to diflunisal in the treatment of chronic lumbar pain. Naproxen and diflunisal show adverse effects similar to the placebo[10] **(A)**.

The use of diflunisal, 500 mg, twice a day for four weeks is superior to acetaminophen 1000 mg, four times a day, in pain reduction and disability of patients with chronic lumbar pain[11] **(A)**.

Ketorolac tromethamine, in 60 mg single dose (intramuscular injection) shows to be effective in the treatment of lumbar pain, showing reduction in the intensity of pain in over 30% in 63% of cases. The main adverse effects found due to the use of this drug are: nausea, paresthesia, sleepiness, xerostomia and pain in the injection site[12] **(A)**.

Selective COX-2 inhibitors

Nimesulide in 100 mg dose, twice a day, shows to be effective in pain reduction in patients with lumbar pain. Nausea, abdominal pain, headache, and vertigo are this drug's main side effects[13] **(A)**.

Highly selective COX-2 inhibitors

Etoricoxib in daily doses of 60 mg and 90 mg is effective in improvement of pain intensity, showing average variation in the Visual Analogue Scale (VAS, 0 to 100 mm) of 12.94 ± 15.5 mm and 10.29 ± 13.3 mm in the four initial weeks of treatment and of 10.5 ± 12.2 mm and 7.5 ± 12.70 mm within twelve weeks of treatment, for the respective doses of 60 mg and 90 mg/day. Side effects occur in 49% of the patients in the placebo group, in 64% of patients in the etoricoxib 60 mg/day treatment group, and in 59% of the patients in the etoricoxib 90 mg/day, being the most common: headache, nausea, diarrhoea, upper respiratory tract infection, worsening in pain, lower limb edema, fatigue, dysgeusia, urinary tract infection, dizziness, abdominal pain, epigastric discomfort, and cough[14,15] **(A)**.

The effectiveness of etoricoxib 60 mg/day in pain alleviation and improvement in function is comparable to the use of a high dose of diclofenac (150 mg/day)[9] **(A)**.

Rofecoxib, in daily doses of 25 mg and 50 mg, is effective in the improvement of pain intensity, presenting average variation in Visual Analogue Scale (VAS, 0 to 100 mm) of 13.5 mm and 13.81 mm compared to the placebo within four weeks of treatment, for the respective doses of 25 mg and 50 mg/day (CI = 95%; RR = 39%; NNT = 5; $p < 0.001$). Side effects occur in 40.8% of patients in the placebo group, in 48.1% of patients in the rofecoxib 25 mg/day treatment group, and in 46.3% of patients in the rofecoxib 50 mg/day treatment group,

being the most common: headache (10.1%, 8.2% and 6.6%), diarrhoea (3.5%, 7.3% and 4.8%), and upper respiratory tract infection (4.4%, 3.9% and 5.7%) in the placebo, rofecoxib 25 mg/day and rofecoxib 50 mg/day groups, respectively. In general, rofecoxib in daily dose of 50 mg does not present superiority compared to recoxib in daily dose of 25 mg[16] **(A)**.

Approximately 2/3 of patients receiving treatment with rofecoxib feel significant reduction in pain within about two days of treatment. However, pain alleviation can be felt within merely two hours after the first dose[17] **(A)**.

In 2004, rofecoxib was pulled from the market due to fear that this drug could increase probability of myocardial infarction or EVA after a long period of continued use[17] **(A)**.

Valdecoxib, in daily dose of 40 mg, is effective in the improvement of pain intensity, showing average variation in the Visual Analogue Scale (VAS, 0 to 100 mm) of 41.9 mm compared to 31.1 mm in the placebo group within four weeks of treatment (CI = 95%; RR = 16%, NNT = 6, $p < 0.001$). Side effects occur in 25% of patients in the placebo group and in 35% of patients in the valdecoxib 40 mg/day treatment group, being the most common: headache (6% and 9%), upper respiratory tract infection (4% and 5%), abdominal pain (less than 1% and 4%), dyspepsia (less than 1% and 3%), dizziness (0% and 3%), and diarrhoea (5% and 1%) in the placebo and valdecoxib 40 mg/day groups, respectively[18] **(A)**.

Valdecoxib was pulled from the market in 2005 due to the possibility that its continued use could cause thrombotic cardiovascular events[18] **(A)**.

Celecoxib, in 200 mg dose, twice a day, over six weeks, improves in at least 30% the pain intensity in, approximately, 65% of the patients treated (CI = 95%; RR= 39%; NNT = 5). Most common side effects to the treatment are: headache (5.8% to 7.2%), nausea (4.2% to 5.8%), sleepiness (3% to 4.5%), dizziness (4%), diarrhoea (3.7%), fatigue (2.7%), constipation (2%), prurience (0.3% to 1.2%), xerostomia (1%), and vomiting (0% to 0.8%). Celecoxib in 200 mg dose twice a day, shows to be more effective if compared to tramadol hydrochloride (mild opiate) in 50 mg dose, four times a day, and shows less reported side effects[19] **(A)**.

The association of celecoxib (approximately 3 mg/kg to 6 mg/kg a day) with pregabalin (approximately 1 mg/kg a day) for four weeks, also shows to be effective in the treatment of chronic non-specific lumbar pain, showing average reduction in pain intensity of 38.2% [20] **(A)**.

Combination of NSAIDS plus steroid plus muscle relaxants

The use of non-steroidal anti-inflammatory drugs such as tiaprofenic acid (300 mg, twice a day), piroxicam (20 mg, one to two times a day), and meloxicam (7.5 mg, once a day) in association with one steroid (betamethasone) and one muscle relaxant (tetrazepan) shows to be effective in the treatment of patients with chronic non-specific lumbar pain, showing pain reduction of five to six points in a total of ten points in the Visual Analogue Scale (VAS, 0 to 100 mm). The main adverse effects relating to this association are epigastric pain and moon-face syndrome[21] **(A)**.

Recommendation

Non-selective COX inhibitor non-steroidal anti-inflammatories are effective for pain management in patients with chronic lumbar pain. It is recommended indometacin, 25 mg, three times a day for six weeks; piroxicam in daily dose of 20 mg; diclofenac in daily 150 mg for four weeks, or naproxen 550 mg, twice a day, for fourteen days. Although non-selective NSAIDs are well tolerated, these drugs are associated with mild to severe gastrointestinal complications, generally, after long-term use[7-12] **(A)**.

Selective COX-2 inhibitor non-steroidal anti-inflammatories such as nimesulide 100 mg, twice a day and meloxicam 7.5 mg, once a day in association with one steroid (betamethasone) and one muscle relaxant (tetrazepam) show to be effective in pain reduction in patients with lumbar pain[13,21] **(A)**.

Highly selective COX-2 inhibitor non-steroidal anti-inflammatories such as celecoxib in 200 mg dose, twice a day during six weeks and etoricoxib 60 mg/day are effective in pain management in patients with chronic lumbar pain[8,14,15,19] **(A)**.

Although Highly selective COX-2 inhibitor non-steroidal anti-inflammatories are associated with less incidence of gastrointestinal events, studies have hypothesized the increase of cardiovascular risk. However, it must be taken into consideration that the time of use of the drug is a determining factor for this risk, having been observed an increase in cardiovascular events after six months of treatment[22] **(C)**.

The increase in cardiovascular risk is also related to advanced age, hypertension, previous myocardial infarction, previous cardiovascular disease, rheumatoid arthritis, chronic renal disease, and chronic obstructive lung disease, among other factors[23] **(C)**.

3. What is the benefit of opiates and their derivatives in patients with non-specific lumbar pain and when should those be indicated? For how long should those be employed?

Opiates versus placebo

Tramadol in association with Paracetamol (T/P) versus Placebo

The use of tramadol in association with paracetamol has significant impact in the improvement of pain, dysfunction, and quality of life, deriving from chronic non-specific lumbar pain[24] **(A)**.

The use of tramadol in association with paracetamol provided improvement of pain, dysfunction, and quality of life, deriving from chronic non-specific lumbar pain of moderate to severe intensity (VAS ≥ 40 mm) within ninety days of treatment with good safety profile[24] **(A)**.

Study involving participants used initial dose of one-four tablets (37.5/325 mg per tablet) to a maximum of eight tablets/day in four daily intakes, being this titulation performed within ten days. Final evaluation showed a pain control ≥ 30% in the PVA scale (0-100). By the end of treatment (ninety days) the T/P group obtained better results compared to placebo with RRR = 23% (CI95% 5% to 41%); ARR = 13.7% (CI 95% 2.9% to 14.5%); NNT = 7 (CI95% 4 to 35). This effect was maintained also to the outcome of ≥ 50% of improvement in the VAS scale within the same ninety days: RRR = 16% (CI 95% 0% to 32%); ARR = 10.6% (CI 95%); NNT = 9 (CI 95%). Tramadol/APAP also improved dysfunction scores (RDQ) with decrease of 4.1 vs. 2.6 ($p < 0.023$) compared to the placebo and also quality of life score (SF-MPQ): decrease of 8.4 (P/T) vs. 4.8 (placebo) with $p = 0.021$. Adverse effects were greater in T/P group compared to the placebo (CI 95%) NNT = 5 (CI 95% 4 to 8). The most common tramadol effects are: nausea (13% vs. 3.2% placebo; $p = 0.001$), sleepiness (12.4% vs. 1.3% placebo; $p < 0.001$), and constipation (11.2% vs. 5.1% placebo; $p = 0.031$). No severe adverse effects were observed over the ninety days of treatment. Average dose of tramadol was 4.2 tablets/day[24] **(A)**.

Tramadol in monotherapy versus Tramadol/Paracetamol

The use of tramadol in association with paracetamol (37.5/325 mg) showed the same outcomes of tramadol by itself (50 mg) with less side effects in a ten-day treatment cycle for non-specific subacute lumbar pain (ten to forty-two days)[25] **(A)**.

It was started with four daily intakes with dose titulation within three days up to maximum eight intakes P/T (300/2600 mg) and P (400 mg). The drug cycle was maintained for ten days. Patients global satisfaction with the treatment within ten days was 72.5% (P/T) and 72.9% (T) and the final VAS levels were 27.9 (P/T) and 24.8 (T), with no significant difference between the groups. However, even not having interfered with global satisfaction, the number of side effects in the P/T group was significantly lower than P group: (30/59 [50.8%] vs. 44/60 (73.3%; $p = 0.019$). Two of the effects had higher significance: nausea 8 (13.6%) in the P/T group vs. 21 (35.0%) in the P group with $p < 0.012$ and dizziness/vertigo 3 (5.1%) in the P/T group and 15 (25%) in the P group with $p < 0.006$ (CI 95%; RR = 16%; NNT = 5). No severe adverse effects were reported[25] **(A)**.

Buprenorphine Transdermal System (BTDS) in monotherapy

In patients with chronic lumbar pain with no distinction regarding etiology (nociceptive or neuropathic), the use of buprenorphine transdermal patch was effective in pain management over the course of four weeks with good safety profile[26] **(A)**.

The buprenorphine transdermal system (BTDS) in 5, 10, and 20 ug/h doses, being the initial dose 5 ug/h with weekly titulation of 5 ug/h or 10 ug/h until attaining adequate analgesia, with maximum dose of 20ug/h, reduces daily pain within four weeks (Visual Analogue scale: 37.6 ± 20.7 mm versus 43.6 ± 21.2 mm, $p = 0.0487$; ordinal pain scale (0-5: no pain, little pain, moderate pain, severe pain, and excruciating pain: 1.7 ± 0.6 versus 2.0 ± 0.7, $p = 0.0358$[26] **(A)**.

However, there is no significant difference between the groups in the functionality and quality of life scores. The following adverse effects are greater in the BTDS group than in the placebo group: nausea (38.4% vs. 16.9%, $p < 0.0330$), and sleepiness: (30.1% vs. 6.2%, $p < 0.0010$). No statistically significant differences were found between the groups in the following adverse effects: constipation, vomiting, prurience, and dizziness. No severe adverse effects were observed either with the use of buprehorphine transdermal system during four weeks of use[26] **(A)**.

Extended release hydromorphone in monotherapy

Patients using opiates due to moderate to severe chronic non-specific lumbar pain showed good management of pain with the use of extended release hydromorphone compared to the placebo[27] **(A)**.

Initially, a hydromorphone titulation was executed (available in doses of 4, 8, 16, and 32 mg) with initial dose equivalent to the previously used opiate with the use of morphine/hydromorphone equivalence = 5:1.

Posology performed in one daily intake. After that, the dose was titulated with increments of maximum two doses, weekly, up to maximum of 64 mg/day (average 37.2 mg/day). Starting from a numeric pain scale, after initial drug titulation, of 3.1 and 3.2 units in each group, the observed reduction in pain was lower in the hydromorphone group (+ 0.2 units) than in the placebo group (+ 1.6), with $p < 0.001$, between the groups by the end of twelve weeks. With 60.6%, patients of the hydromorphone group had at least 30% average reduction in the daily pain scale (0-10) compared to 42.9% in the placebo group ($p = 0.01$), whereas there was > 50% average reduction in the daily scale 42.4% of the hydromorphone group and 24.1% of the placebo group ($p = 0.01$). Statistically, there was also significant change in the disability scale of twenty-four points, with average variation in the hydromorphone group of 0.0 vs. + 1.0 in the placebo group ($p < 0.005$), by the end of twelve weeks. The main adverse effects were constipation, nausea, vomiting, sleepiness and headache. Between the groups, significant differences were shown in: constipation (7.5 vs. 3.7%); arthralgia (6.0% vs. 2.2%), and sinusitis (4.5% vs. 0.7%). One severe adverse effect was reported, attributed to abstinence syndrome (vomiting with dehydration and renal insufficiency) during the opiate suspension phase in the placebo group[27] **(A)**.

Er oxymorphone (extended release) monotherapy versus placebo

Extended Release Oxymorphone (L) is effective in the treatment of lumbar pain compared to placebo in habitual opiate user patients[28] **(A)**.

This study used initial dose of OPANA ER 1x/day determined by the equivalence to the opiate the patient had been using (Morphine/Oximorphone = 3:1). Next the dose was titulated in 10 mg every three to seven days until reaching pain control (VAS ≤ 40 mm) during three to five days. This period lasted four weeks and the average dose in the titulation phase was about 105 mg/day. After stabilizing this titulation phase, the VAS scale addition (0-100) until the final twelve-week visit was of 31.6mm in the placebo group versus 8.7mm with OPANA ER ($p < 0.0001$). Nausea, constipation, headache, and sleepiness were the most common adverse effects, however, there was no statistical difference between groups during the twelve-week treatment period. In the titulation period (four weeks) 49% experienced nausea, 29% constipation, 29% headache, 28% sleepiness, 22% vomiting, and 19% prurience[28] **(A)**.

Er oxymorphone (extended release) vs. Cr oxycodone (controlled release) versus placebo

The use of oxymorphone or oxycodone in equivalent doses is more effective than the placebo in the control of pain in chronic non-specific lumbar pain with the same safety profile between both opiates[29] **(A)**.

One study involving 213 patients with moderate to intense intensity non-specific lumbar pain in opiate users for at least three days divided the patients into three groups. One group received extended release (ER) oxymorphone, another received controlled release (CR) oxycodone, and the third group received placebo. The patients passed through a phase of seven to fourteen days in which they received oxycodone or hydromorphone in 12/12 h posology with equivalence to the previously used opiate. Pain control was monitored without use of rescue morphine sulfate in dose higher than 30 mg/day. The hydromorphone group received 10 mg in each dose, daily up to 100 mg (average 79.4 mg/day); the oxycodone group increased 20 mg in each dose, daily, up to 220 mg (average 155 mg/day). From then on, a treatment phase was maintained for eighteen days. ER Oxymorphone and CR Oxycodone were superior to the placebo for change in pain intensity (VAS 0-100) with -18.21 (95% CI, -25.83 to -10.58; $p < 0.0001$) for ER oxymorphone, and -18.55 (95% CI, -6.12 to -10.98; $p < 0.0001$) for CR oxycodone[29] **(A)**.

In the post-titulation treatment phase only two effects were significantly greater in the opiates group: constipation ($p < 0.01$), and sedation ($p < 0.005$), but in the final score there was no statistical difference between the three groups in this phase, just as no severe adverse effects were observed (SAE). However, in the titulation

phase the adverse effects were significantly greater in both opiate groups compared to the placebo, with no differences between the two opiates. Also in this phase, three SAE were observed: respiratory frequency drop in one patient, CPK increase and abdominal pain in another patient, and worsening of lumbar pain in a third patient[29] **(A)**.

Opiate versus NSAID

Tramadol in monotherapy Versus Celecoxib in monotherapy

The use of celecoxib (200 mg 2 x/day) was better than tramadol (50 mg 4 x/day) in the treatment of chronic non-specific mechanical lumbar pain of moderate to severe intensity, in addition to having less side effects[30] **(A)**.

Two studies were conducted parallelly, having as answers equal reduction of 30%. In study number one, by the end of six weeks, 63.2% of patients in the Celebra® group vs. 49.9% in the tramadol HCl group, reached over 30% of pain reduction by the NSR scale (0-10) with $p < 0.001$. In study number two, by the end of six weeks, 64.1% of answerers in the Celebra® group vs. 55.1% in the tramadol HCl group ($p < 0.008$). In the Celebra® group at least one adverse effect was reported in 31.1 and 30.6% of patients in each study (most common being headache in 7.2%, and 5.8%, nausea: 4.2%, and 5.8% and dizziness: 4.0%, and 4.0%). In the Tramal® group: 45.8%, and 46.7%, being the most common: nausea: 19.5%, and 15.7%; dizziness: 14.1%, and 12.6%, and 9.5%, and sleepiness 10.9% - $p < 0.0001$[30] **(A)**.

Naproxen versus oxycodone vs. Oxycodone plus extended release morphine

There is greater benefit in the administration of extended release opiate associated with short-acting opiate compared to isolated short release opiate and to naproxen in the treatment of non-specific mechanical lumbar pain during sixteen weeks of treatment[31] **(B)**.

Three groups were tested during sixteen weeks: naproxen 250 mg 4 x/day (N), oxycodone 10 mg 4 x/day (O), and oxycodone plus extended release morphine (O/M) titulated according to the patient's pain up to the maximum dose of 200 mg of opiate a day. Average pain with sixteen weeks in the experimental phase showed lower VAS scores in the O/M group compared to O and N groups. By the end of sixteen weeks, pain levels were: 65.5 (group N), 59.8 (group O), and 54.9 (group O/M) with $p < 0.001$, but there were no statistically significant differences between groups in the dysfunction scores. Regarding side effects, the most common were xerostomia, sleepiness, headache, constipation, and nausea. The O/M group had a higher quantity of side effects compared to the other groups ($p < 0.001$), however, those were less intense than in the other groups[31] **(B)**.

Recommendations

Patients with chronic non-specific lumbar pain, analyzed in the controlled and randomized studies, who benefitted from the use of opiates were those who had moderate to severe lumbar pain, referred to as VAS ≥ 40 mm, despite using analgesics, anti-inflammatories, and even opiates[24-31] **(A)**.

The use of tramadol in association with paracetamol (37.5/325 mg) from four to eight doses in a maximum period of twenty-four hours over ninety days has positive impact in the improvement of pain, dysfunction, and quality of life deriving from chronic non-specific lumbar pain[25] **(A)**.

The use of tramadol in association with paracetamol (37.5/325 mg) from four to eight doses in a maximum period of twenty-four hours over ninety days has shown the same outcome of tramadol isolatedly (50 mg) with less side effects in a ten-day treatment cycle for non-specific subacute lumbar pain (ten to forty-two days)[25] **(A)**.

In patients with chronic lumbar pain with no etiology distinction (nociceptive or neuropathic), the use of buprenorphine transdermal patch was effective in the control of pain over the course of four weeks with good safety profile[26] **(A)**.

Opiate-user patients due to chronic non-specific lumbar pain, less than six months, moderate to severe, showed good control of pain for twelve weeks with the use of extended release hydromorphone compared to placebo[27] **(A)**.

Extended release oxymorphone (L) for four weeks is effective and safe in the treatment of lumbar pain compared to the placebo in habitual opiate user patients[28] **(A)**.

The use of oxymorphone or oxycodone for eighteen days in equivalent doses between themselves are more effective than placebo in the control of pain in chronic non-specific lumbar pain with the same safety profile in both opiates[29] **(A)**.

The use of celecoxib (200 mg 2 x/day) was better than tramadol (50 mg 4 x/day), during six weeks, in the treatment of moderate to severe intensity chronic non-specific mechanical lumbar pain, in addition to having less side effects[30] **(A)**.

There is greater benefit in the administration of extended release opiate associated with short-acting opiate compared to the short-acting opiate isolatedly, and to naproxen in the treatment of pain from non-specific mechanical lumbar pain during sixteen weeks of treatment[31] **(B)**.

4. Is the use of antidepressants effective in the treatment of pain from chronic non-specific lumbar pain?

Duloxetin, first-line drug[32-35] **(A)**, in a 60 mg/day dose is effective within up to twelve weeks, showing average improvement of two to three points in the Visual Analogue Scale - VAS), 56% chance of improvement of at least 30% of pain, and 47% chance of improvement of 50% of pain. The 120 mg/day dose had the same beneficial effect, however, for a longer period than three months[32,34] **(A)**.

All recommended doses offer variable and individual benefit to the improvement of function and quality of life that extend after the third month; 64% of the people report adverse events with use of duloxetin in the 20 mg/day dose, 36% to 67% in the 60 mg/day dose and 73% in the 120 mg/day dose (CI = 95%; RR = 32%; NNT = 7; $p < 0.001$). The severe side effects of this drug are: ashtma, myocardial infarction, dyspnea, precordial pain, transient ischemic accidents (TIAs), toxic myopathy, muscular weakness, and vertigo, afflicting 2.6% of users. In the 60mg/day dose, the most common effects are nausea 7.3% to 22%, insomnia 7.3% to 9%, headache 4.8% to 10%, xerostomia 9.7% to 11%, obstinacy 2.4% to 9%, sleepiness 7%, diarrhoea 2.4% to 11%, fatigue 9%, and dizziness 2.4% to 10%[32-35] **(A)**.

Escitalopram in 20 mg/day dose has similar results to duloxetin. The side effects of these drugs appear in 36% of users, being the most common: xerostomia 10.2%, insomnia 7.6%, nausea 5.1%, dizziness 5.1%, headache 2.5%, inappetence, and obstinacy. It was not possible to calculate the number required to treat NNT, because the results obtained by the pain intensity scale (Likert scale from zero to ten), primary outcome, are presented in the article in a general manner, showing only the average pain reduction in the groups treated with duloxetin and escitalopram (escitalopram: 6.3 (1.5) and duloxetin: 6.4 (1.4)[35] **(A)**.

Nortriptyline, in progressive dose of 25 mg/day to 100 mg/

day, is effective for at least eight weeks of treatment, with average pain reduction of 22%. This drug's side effects include xerostomia 82.1%, insomnia 71.4%, sedation 60.7%, postural hypotension 60.7%, obstipation 42.9%, sudoresis 32.1%, and heart palpitation 10.7%[37] **(A)**.

One study compared maprotiline, norepinephrine reuptake inhibitor, and paroxetin, also norepinephrine reuptake inhibitor, for the improvement of pain in patients with chronic non-specific lumbar pain. It was concluded that maprotiline in the maximum dose of 150 mg/day, for eight weeks, shows to be effective, reducing pain in 45% to 27% if compared to the placebo ($p = 0.023$), and 26% if compared to paroxetin (30 mg/day for eight weeks; $p = 0.013$). The side effects appear in 90% of patients, being the most reported: xerostomia 85%, sedation 80%, insomnia 70%, orthostatic hypotension 50%, constipation 50%, heart palpitation 10%, and sudoresis 5%[38] **(A)**.

Bupropion, in 300mg/day dose, is ineffective as well as other selective serotonin reuptake inhibitor antidepressants such as paroxetin of up to 30 mg/day (CI = 95%; RR = 32%, NNT = 17; $p = 0.013$)[36-38] **(A)**.

The main cause of therapeutic abandonment are the side effects, which showed to be proportional to doses, as were the beneficial effects[32-35,37,38] **(A)**.

Recommendation

Antidepressants play an important role in pain management and treatment of chronic non-specific lumbar pain, with variable effectiveness. Antidepressants with associated adrenergic effects, such as tryciclical and dual antidepressants, show better results than selective serotonin reuptake inhibitors, which, in the most part, show insufficient and questionable results[35,37,38] **(A)**.

It is recommended as first choice the duloxetin in 20 mg/day dose and maximum of 60 mg/day for twelve weeks[32-35] **(A)**.

Another option would be escitalopram in 20 mg/day dose for up to twelve weeks, because it has similar results to duloxetin[35] **(A)**.

The use for over three months is not recommended due to side effects being evident on all studies[35,37,38] **(A)**.

5. What are the advantages of the association of analgesics with muscle relaxants?

Muscle relaxants is one among several prescribed and used treatments for chronic non-specific lumbar pain. Those can be divided into antispastic and antispasmodic. For muscular diseases the antispasmodics have their indications and are divided into benzodiazepines and non-benzodiazepines [39] **(A)**.

There are several muscle relaxants in the market, such as carisoprodol, cyclobenzaprine, orphenadrine, tizanidine among the non-benzodiazepines, and, also, Diazepan® and tetrazepan among the benzodiazepines[39] **(A)**. Diazepan® is a benzodiazepine that has as its rebound effect the muscle relaxation produced by central sedation[39] **(A)**.

A superiority was found in moderate muscle relaxants compared to placebo in the improvement of pain on the eigth day. Tizanidine (2 mg/day + diclofenac 50 mg/day for eight days; $p < 0.05$) and cyclobenzaprine (5 mg/day for seven to ten days, $p = 0.003$) were the most studied for chronic lumbar pain[41,42] **(B)**.

Tizanidine (2 mg/day + diclofenac 50 mg/day for eight days; $p < 0.05$) and baclofen (30-80 mg/day for fourteen days, $p < 0.05$) promote increase in postural hypotension and increase in the fall risk among the elderly, therefore should be used carefully[41] **(B)**.

Cyclobenzaprine is a tryciclic with mild antidepressant effect used as muscle relaxant[39] **(A)**.

However, there is no evidence to determine if there is superiority of one relaxant over the other for chronic non-specific lumbar pain. Two studies verified tetrazepan's superiority over the placebo for chronic non-specific lumbar pain in 50 mg dose, three times a day for ten to fourteen days with significant improvement of pain in the seventh and eighth day (RR = 2.04, CI 95%; $p < 0.001$)[40] **(B)**.However, this medication is no longer prescribed as a muscle relaxant due to the sedation it causes, as well as its risk of dependence[40] **(B)**.

Muscle relaxants are associated to several adverse events, such as: sedation, sleepiness, dizziness, visual turbidity, nausea, and vomiting. Carisoprodol presents potential psychological and physical dependence due to its active metabolite (RR = 2.04, CI 95%; $p < 0.001$)[40] **(B)**.

Cyclobenzaprine must be contraindicated in cases of glaucoma or intraocular hypertension. Care should be exercised also with patients with any cardiopathy, because its tryciclic structure may cause severe arrhythmia, worsening of congestive heart conditions, and of myocardial function in patients with history of myocardial infarction[40] **(B)**.

In a review, it was recommended that the first option for treatment of CLBP should be the use of non-steroidal anti-inflammatories (NSAIDs) and antidepressants in view of the lack of adequate data for the indication of muscle relaxants[41] **(A)**.

Further discouraging the use of those, the American Pain Society and the American College of Physicians do not recomend them as a first option, but other drugs such as acetaminophen and NSAIDs(D).

Recommendation

The use of muscle relaxants is not recommended as a first option for chronic non-specific lumbar pain in view of the lack of safe information in the medical literature to support that their use will provide pain alleviation regardless of the side effects.

Conservative Non-Pharmacological Treatment

6. What are the physical means used?

Ultrasound

Ultrasound is a modality of deep heat that employs high-frequency acoustic vibrations, over the human audible range, defined by frequencies over 17.000 Hz. Therapeutic frequencies range from 0.8 MHz to 1 MHz wavelength of 0.15 cm[43] **(B)**.

The influence of ultrasound was studied for the improvement of: disability, pain, walking performance, trunk muscular strength, resistance, mobility, quality of life, and the depression scores in patient with chronic non-specific lumbar pain. The study compared three groups among which group number one (n = 20) performed electrostimulation for fifteen minutes, four electrodes in L2-L4, 50 Hz 50 ms, plus another forty-five minutes of supervised physical exercise; group number two (n = 19) performed ultrasound for ten minutes, in 1 MHz frequency, power of 1 W/cm^2, with 5 cm^2 transducer area in slow circular movements in the lumbar paravertebral region, as well as supervised physical exercises for forty-five minutes after ultrasound; and group number three (n = 20) executed the same exercises as group one and two without any other intervention. The intervention frequency in all groups was three times a week during six weeks. It was observed that there was no statistical significance among the groups, all presented improvement of pain, functional capacity, muscular strength and positive values in the assessment scores of depression and quality of life ($p < 0.05$)[44] **(B)**.

The assessment of quality of life, performed by the Short Form-36 (SF-36), showed improvement in the last evaluation, six weeks, that jumped from forty-four (44-88) to eighty-eight (66-99) for group number two if compared to group number three that had control improvement of fifty-two (44-88) to seventy-seven (65-100) ($p = 0.001$)[44] **(B)**.

In another study, group number one was submitted to aerobic exercises plus home exercises, with that, there was a statistically significant improvement in the severity of pain within one month of follow-up, when compared to the pre-treatment levels (Visual Analogue Scale (VAS) 0-100 mm = 57.05 ± 24.5 before intervention; 34.1 ± 27.6 in the assessment after one month of intervention - ($p = 0.002$). Group number two performed surface heating with heated pads in the lumbar region for fifteen minutes. These patients also received continuous ultrasound in the frequency of 1 MHz and 1.5 W/cm intensity; the transducer covered a 5 cm area, and slow and circular movements were applied over the paravertebral region for ten minutes. This group received transcutaneous electrical stimulation over the nerve (TENS; 30-40 Hz, using the conventional method) for fifteen minutes, and conventional physical therapy three times a week for six weeks. With this process, there was improvement in the severity of pain (VAS = 61.2 ± 20.5 before intervention to 28.8 ± 28.1 after one month from the procedure ($p = 0.001$)), thus showing there is little difference among groups ($p = 0.0001$). Group three had the home exercise intervention, with improvement in severity of pain of 56.0 ± 19.9, VAS before treatment, to 33.6 ± 24,3 after one month ($p = 0.006$). It is concluded that there were no significant differences among the three groups in intensity of pain, disability, and psychological condition before and after treatment. However, after one monthfollow-up the group that had ultrasound and TENS had a 47% higher improvement than the other groups ($p = 0.002$)[45] **(B)**.

Recommendation

The use of continuous ultrasound is recommended in the 1 MHz frequency, power of 1 W/cm^2, with 5 cm^2 transducer area, in slow circular movements in the lumbar paravertebral region during ten minutes, plus supervised physical exercise working lumbar and abdominal muscles with five minutes for warm-up, and five minutes of final stretchings, three times a week during six weeks aiming the improvement of pain in chronic non-specific lumbar pain[44,45] **(B)**.

Ultrasound must be contraindicated in the cases where there is risk of gaseous cavitation in fluid means such as eyeball and pregnant womb, over plastic components of endoprosthesis, metacrilate, heart which in addition to cavitation could generate swirling; growth epiphysis, and areas with broken skin, and patients with cognitive and intelectual impairment. It is also contraindicated the use in tumours in view of the risk of proliferation. It should be avoided in case of anesthetic areas, articular facets close to the spine exposure area such as laminectomy[45] **(B)**.

Thermal waters

This randomized, double-blind, controlled study conducted by Ágata Kulisch et al. which included seventy-one patients with chronic non-specific lumbar pain, of both genders, aged twenty-five to seventy years submitted to twenty minutes a day of treatment sessions with medicinal waters or tap water, both at a 34°C temperature, in twenty-one sessions. Both groups were submitted to electrotherapy. The parameters of this study were measured at zero time, immediately after treatment, and after fifteen weeks according to VAS (0-100 mm)[46] **(B)**.

After treatment, there was significant improvement in all of the parameters in the thermal waters group. There was more evident improvement of pain after fifteen weeks. The comparison of the intervention group with the control revealed a statistically significant difference in the Visual Analogue Scale (VAS). Within three weeks, patients who received thermal water showed significant therapeutic response, with a VAS decrease in comparison with the control group (-14.8 (confidence interval 95% (CI) from -18.9 to -10.7 vs. -8.2 (95% CI -14.1 to -2.4), $p < 0.05$). After fifteen weeks, the changes in VAS between the initial and final values of the study showed to be significantly higher in the thermal waters group (-17.6 (CI 95% -22.9 to -12.4) vs. -5.2 (95% CI -13.9 to 3.4), $p < 0.05$)[46] **(B)**.

Recommendation

The immersion for twenty minutes daily either in medicinal or in tap water is recommended, both in a 34°C temperature, for three weeks for improvement of pain in chronic non-specific lumbar pain.

Short waves

In a prospective experimental study, randomized, involving ninety-seven patients of both genders aged between twenty and eigthy years, with chronic lumbar pain complaints, a protocol was conducted with shortwave diathermy for pain relief. The patients in the intervention group, i.e., group A, were submitted to short wave diathermy treatment in the lumbar region, for fifteen minutes, three times a week, over six weeks. For these patients it was also prescribed Meloxicam 15 mg a day, orally administered[47] **(B)**.

The statistically significant improvements arised after the end of the third week, however, in most of these patients the improvement could only be observed by the end of the sixth week of treatment, with reduction in the scale (0-34 points including VAS). The combined pre-treatment scores of the groups were: in group A, equal to 20.44 ± 3.02 and, in group B, equal to 20.10 ± 3.51. By the end of the sixth week, the group A score was 6.44 ± 3.06 whereas group B score was 13,38 ± 3.10 ($p = 0$)[47] **(B)**.

Recommendation

The use of shortwave diathermy is recommended in the lumbar region, for fifteen minutes three times a week over six weeks, for the improvement of pain in chronic non-specific lumbar pain[47] **(B)**.

7. What is the role of electrical stimulation in chronic non-specific lumbar pain?

The main forms of electrical stimulation intended for analgesia are TENS, transcutaneous electrical neurostimulation, and PENS, percutaneous electrical neurostimulation[48] **(A)**.

The transcutaneous electrical neurostimulation, TENS, can be high-frequency (> 50 Hz) with intensity below the needed to promote muscle contraction, called sensory intensity, or low-frequency (< 10 Hz), with intensity capable of producing muscle contraction[48] **(A)**.

Regarding PENS, there is a combination of acupuncture and electrical current[48] **(A)**.

It is believed that PENS should be considered as a analgesic modality to ease an exercise program for the population with CLBP[49] **(A)**.

PENS is contraindicated for patients: who use pacemakers, with the exception of when authorized by the cardiologist; in pregnant

women application should be avoided during the first three months, especially, in the lumbar and abdominal regions; epileptic patients, cardiac conditions; people with Encephalic Vascular Accident sequelae should not receive applications in face or neck; and those with cognitive impairments[49] **(A).**

In a bibliographical research of original articles in English, randomized, prospective, double-blind, and controlled, it was observed a great superiority of analgesic interventions based in the use of electrical stimulation over placebo or multimodal exercises[50] **(A)**.

Prospective study with forty-one patients with chronic lumbar pain, randomized in two groups, being that in group one (n = 21) a program with TENS and exercises was administered, and group two (n = 20), accepted as the control group, received only exercises. Both programs were performed three times a week over eight weeks, in clinic[50] **(A)**.

Electrical stimulation was administered with the patient in the prone position for fifteen minutes and in dorsal decumbent position for fifteen minutes. The electrodes of the prone position were placed on the L2-L4 levels along the motor points of the paraspinal musculature, and the ones of supine position were placed in the motor points of the muscle in abdominal external oblique. The symmetrical biphasic waveform was applied in the 50 Hz frequency and 50 ms of phase time. The current intensity was set, separately, one at a time, for each patient until an apparent muscle contraction was established (70-120 mA). The stimulation was applied at ten seconds of contraction and ten seconds of relaxation[50] **(A)**.

There was significant improvement in all pain parameters in both groups after treatment, however, with greater improvement in the intervention group ($p < 0.001$). The measurements performed on group one by the ODQ scales at zero time were 36.66 ± 9.53 and by the end of treatment, 6.57 ± 5.53, whereas in group two were 37.22 ± 17.04, and by the end, 19.22 ± 13.99 ($p = 0.001$). When evaluated by PDI (0-50), group one started from nineteen (10-45) to four (0-23) whereas group two went from twenty-two (12-64) to 9.5 (0-48) ($p < 0.001$)[50] **(A)**.

Another randomized clinical study, with two hundred men and women aged over sixty-five years, evaluated patients with chronic lumbar pain to ascertain PENS effectiveness, either with or without general conditioning and aerobic exercises GCAE, in order to reduce pain and improve physical function. The participants were randomized to receive: 1) PENS plus control-PENS, brief electrical stimulation to control treatment expectancy; 2) PENS + GCAE; 3) PENS control puls GCAE, twice a week over six weeks. The intervention group had the needles inserted bilaterally in the position corresponding to the spinal spaces of T12, L3, L5 and S2 corresponding to the motor point of the piriform muscle. The stimuli were of thirty minutes only in T12. The exercises performed in place aimed an increase in strength and flexibility with aerobic component and lasted sixty minutes. The patients oriented to perform them at home aimed aerobic exercises with walking and, also, flexibility. All four groups had significant reduction in pain (ranging from -2,3 to -4.1 in the McGill Pain Questionnaire short form) sustained for six months. In the GCAE groups it was verified a greater decrease in fear post-intervention and at six months than in the non-GCAE groups[51] **(A)**.

However, when compared to other analgesic modalities, PENS shows superiority over TENS while this one is equated with other therapies such as deep ultrasound diathermy[51] **(A)**.

Tens versus USG

Comparison studies between the effects of electrical stimulation (ES) and ultrasound (US) in pain therapy, in disability, muscular strength, trunk, walking performance, spine mobility, quality of life (QL), and depression in patients with chronic non-specific lumbar pain (CLBP). A total of fifty-nine CLBP patients were included in this paper and those were randomized within three groups. Group one (n = 20) received the exercise and ES program, Group two (n = 19) was submitted to treatment with US and exercises, and Group three (n = 20) was the control group and performed a few conventional exercises. All programs were performed three times a week, over six weeks. The results were improvement regarding quality of life and pain assessed via the quality of life questionnaire SF-36 and their results were compared at the start and finish of intervention. When the groups were compared, the gain was the same ($p < 0.001$) between the group that had electrical stimulation and the one that had TENS, being that the group that had ultrasound (SF-36 scale score of 49 (11-77) to 88(55-100) and in 44(44-88) to 88 (66-99), respectively[52] **(B)**.

Another study randomized sixty patients within three groups: group one had aerobic exercise plus home exercises; group two had physical therapy with surface diathermy patch, ultrasound, TENS and home exercises, and group three performed conventional home exercises. All three therapeutic approaches reduced pain and increased aerobic capacity. However, the results indicated that physical therapy plus home exercises showed greater effectiveness considering psychological aspects[53] **(A)**.

Tens versus massage

The first clinical essays, adequately randomized, compare the transcutaneous electrical stimulation with massage by negative pressure. The light massage used was produced by placing, over the skin, four cups kept in place by light negative pressure. A device maintained light variations to the pressure, slowly, so that a smooth and constant massage was applied to the skin. Electrical stimulation was effected with an active electrode placed firmly at the center of the painful lumbar area, and the second electrode was placed in the lateral leg fascia. Output frequency was set in 4 Hz-8 Hz and, next, current intensity was raised until the patient reported unpleasantness, then this intensity was reduced to a tolerable level. During the session the intensity was adjusted and kept at a tolerable level. This treatment was applied twice a week during thirty minutes with the number of sessions determined by the patient improvement, limited to twenty sessions. CLBP-specific exercises were performed by the end of physical therapies. The results found are of improvement of pain superior to 50% in 85% of patients submitted to TENS against 38% in the massage group[54] **(A)**.

TENS versus PENS

The study we discuss now intended to show the number of necessary PENS sessions to alleviate chronic lumbar pain and for how long the analgesia is sustained. Patients with VAS under 40 mm were submitted to interventions twice a week during eight weeks. Group A (n = 18) received PENS for eight weeks; group B (n = 17) received PENS in the four initial weeks and transcutaneous electrical nerve stimulation TENS in the next four sessions; and group C (n = 18) received TENS during eight weeks. Were evaluated level of pain, degree of physical disability, and the daily ingestion of non-steroidal

anti-inflammatories (NSAIDs), before the first treatment, three days after and in the second, fourth, and eighth weeks of treatment, and, also, one to two months after completing the sessions[55] **(A)**.

During the PENS therapy the level of pain significantly decreased after the second week in groups A (VAS 55 ± 11 to 37 ± 10) and B (56 ± 9 to 36 ± 13) (P 0.05 or 0.01) and the physical impairment and NSAIDs required significantly declined after the fourth week (P 0.05 or 0.01) in Group A. However, this decline can only be observed in the fourth week on Group B (P 0.05 or 0.01). These effects were sustained up to one month of follow-up ($p < 0.01$) in Group A, although they were not sustained in Group B. It was also observed, that in the second month of follow-up the groups did not sustain these effects, even in Group A. In Group C, the level of pain significantly decreased only in the eighth week ($p < 0.05$)[55] **(A)**.

Recommendation

Electrical stimulation and other physical means are seen as an easing path to analgesia to obtain physical rehabilitation based in chronic non-specific lumbar pain-specific physical exercises, since it includes not only gain but also maintenance of amplitude of movement with flexibility stimuli and strengthening of the trunk, abdomen and gluteus stabilizing musculature.

Both therapeutic modalities are recommended with a few reservations regarding contraindications and side effects.

The use of transcutaneous electrical neurostimulation TENS is done in symmetrical biphasic waveform applied with 50 Hz frequency and 50 ms phase. The current intensity should be organized, separately, one by one for each patient, until the apparent muscle contraction is established (60-130 mA). This stimulation must be applied with ten seconds of contraction and ten seconds of relaxation[56-58] **(B)**. The placement of electrodes is suggested on the position of lumbar vertebrae two to lumbar four over the motor points of the spinal erection musculature, bilaterally[51] **(A)**.

The use of TENS has an advantage that it can be done at home, without the need of a trained professional to apply the electrodes. To do so, it suffices that the patient be trained and understands the instructions given for the correct use, and does not fit the contraindications.

PENS can be recommended with needles inserted, bilaterally, in the position corresponding to the vertebral spaces of T12, L3, L5, and S2, subjected to the motor point of the piriform muscle; apply only thirty minutes of stimuli in T12, and fifteen on the others; twice a week during eight weeks; include exercises that aim increase in strength and flexibility with aerobic component for sixty minutes.

However, the benefits of these modalities, without maintenance with specific exercises, are not enough to maintain long-term analgesia, being only an easing path for rehabilitation-specific exercises[51,59] **(A,B)**.

8. What is the benefit of physical exercise in the treatment of CLBP?

Different models have been proposed for the treatment of chronic non-specific lumbar pain, but no method seems to be more effective than the other[60-64] **(B)**.

Exercise programs are employed in the treatment of chronic non-specific lumbar pain aiming to reduce or eliminate these patients' pain. The exercise programs involve, frequently, aerobic exercises, strengthening, and stretching, as well as orientations to patients[60-64] **(B)**.

General exercises groups that involve stretching, strengthening, and warm-up can reduce pain and the positive effects may persist for up to five years ($p = 0.01$)[60] **(B)**.

Programs such as the one from Spine School in comparison to control group show improvement regarding intensity of pain, functional capacity and lumbar spine mobility[61] **(B)**.

However, comparing the types of treatment such as an example, one intense that includes therapeutic exercises, the posture school, and behavioral therapy with physical therapy, no difference was found[62] **(B)**.

One group of motor control exercises shows significant improvements compared to the individuals that performed general and manipulation/mobilization exercises after eight weeks of treatment[63] **(B)**.

Programs that involve strengthening training also indicate that this type of training improves musculoskeletal fitness, pain and disability after eight weeks, showing this is a safe and effective type of exercise in these individuals' rehabilitation[64] **(B)**.

Manual therapy, spine mobilizations, and spinal column stabilization exercises, aerobic gimnastics classes, involving ten exercise stations, for thirty minutes, during eight weeks, confirmed the improvement of pain in the six and twelve months evaluations. Studies affirm that these exercises, when individually performed, are more beneficial than when performed in group. The evaluations performed were: lumbar flexion, being that the participants would be standing and were invited to slide their hands over the front of their legs until they experienced the first point of pain or the first increase in pain. The distance corresponding to the extremity of the middle finger to the floor was measured with a metric tape, asking to assign the intensity of pain in the Visual Analogue Scale (VAS), where the left side represented no pain and the right side represented the worst imaginable pain. Lumbar extension was measured in the same manner with the individuals sliding their hands below the posterior side of the legs and the same method was used for the assessment of left and right lateral flexion. The straight Leg Raise was performed in supine position the left band and the right (raise the leg straight) was measured by placing an inclinometer (Isomed, Portland) over the tibial tuberosity. The leg was passively elevated and the angle at the first point of pain, or first increase in pain, was read on the inclinometer. The subjects, next, assigned the intensity of pain in the VAS pain line. After a twelve-month treatment, there was an average increase of 8.5 cm in the amplitude of flexion, range extension of 2 cm, 2.5 cm of amplitude of flexion on the left side, 2.7 cm of amplitude of flexion on the right side, 12.6° left SLR range, and 10.5° SLR range in the exercise group. The results of the group treatments were: 12.5 cm flexion; 1.5 cm extension; 2.5 cm left side flexion; 1,3 cm right side flexion; 12.1° to the left and 12.2° to the right, with exception to flexion on the left side and right side. At twelve months, there were statistically significant reductions in VAS (pain) for all movements, except for left lateral flexion, in exercise. At twelve months, twenty-one out of thirty-three individuals (63.6%) who participated in the exercise group reported improvement and twelve out of thirty-three (36.4%) felt they remained in the same condition since starting the study. The average percentage of improvement within twelve months was 62.9% (2%-10% interval). The data regarding the individual treatment group at twelve months was 75.8% of the individuals with improvement in pain (% interval from 12 to 95); seven out of twenty-nine (24.1%) had no changes[65] **(B)**.

Recommendation

Physical exercise is indicated for the treatment of chronic non-specific lumbar pain. However, in the literature are found several types

of exercises, in most of the times, combinations of several types of exercises within the same intervention group. Therefore, there are no decisive evidences to support the superiority of one type of exercise over another for the treatment of chronic non-specific lumbar pain, however, all studies indicate that there is improvement in pain, regardless of the exercise type and frequency[60-65] **(B)**.

9. What is the benefit of acupuncture in the treatment of chronic non-specific lumbar pain?

Acupucnture plus usual care versus usual care isolatedly.

Acupuncture combined with other conservative therapies, such as: physical therapy, NSAID, analgesia, heat therapy, self-care, and postural education is more beneficial than the application of the same therapies isolatedly[66-68] **(B)**.

One study involving fifty-five participants with non-specific lumbar pain of up to twelve weeks showed greater symptomatic and functional benefit with the use of electroacupuncture combined with usual care, e.g., analgesia, NSAID, physical therapy and no TENS in comparison with the performance of the same usual care, isolatedly[66] **(B)**. Electroacupuncture sessions were performed in two weekly sessions, total of ten applications, with attainment of *DeQi* and current flow of 4-6 Hz with pulse duration 0.5 m sec and use of ten to fourteen needles per section in points BL23, BL24, BL25, BL28, DM3, DM4 plus the use of four additional needles in case the pain were irradiated to the leg on the following points: BL36, BL37, BL40, BL54, GB30, GB31. The duration of each session was twenty minutes. The acp plus usual care group show the following results compared to the usual care isolatedly group: (1) Reduction of 4.1 ± 3.9 in the Roland Disability Questionaire (0-18) on the sixth week after starting the treatment (acp group) in comparison 0.7 ± 2.8 (control group) with $p < 0.001$. This was maintained until the ninth week for four weeks after the last treatment with the acupuncture group sustaining reduction of 3.5 ± 4.4 and usual care group 0.43 ± 2.7 with $p < 0.007$ between the groups. On the VAS scale (0-10) there was no statistical difference among groups on the sixth week, however, on the ninth week there was a decrease (-0.2 ± 1,3) on the acupuncture group and increase of (+ 0.7 ± 1.1) on the isolated usual care with significance among groups ($p < 0.02$)[66] **(B)**.

The greatest benefit in the use of acupuncture plus routine orthopedic care, e.g., physical therapy, physical exercises, heat irradiation, spine schools, mud packs, in comparison with isolated routine orthopedic care (ROC), was shown, after six months from the beginning of treatment, one benefit after three months from the last treatment session[67] **(B)**.

Study with application of acupuncture in twelve sessions three times a week and application of needles to the following points: B23, B25, GB30, B40, B60, VB34 plus another four *AhShi* points in the lumbar region in moderate to strong manipulation technique with *DeQi* evocation for thirty minutes shows that the session obtained success rates (reduction ≥ 50% on the VAS scale 0-100) after six months from the start of treatment or three months from the last treatment of 67% (CI 95%: 62-88%) with acupuncture plus ROC vs. 14% (CI 95%: 4-30% with $p < 0.001$) for ROC isolatedly[67] **(B)**.

The greatest benefit in pain and dysfunction of non-specific mechanical lumbar pain with duration of up to six months with application of acupuncture plus auriculopuncture combined with physical therapy compared to the performance of physical therapy isolatedly by the end of treatment cycle of twenty sessions of acupuncture, five times a week within two weeks, plus once a week over ten weeks and another twenty-six weekly sessions of physical therapy distributed along twelve weeks. This benefit extended up to nine months follow-up[68] **(B)**.

DeQi sensation must be evoked and the permanence of needles (0,3 mm x 40 mm) must be of ten to thirty minutes. Twenty needles with nine bilateral points and two isolated points were used in the systemic acupuncture: BL23, BL25, BL31, BL32, BL40, BL60, VB34, SP6, VG3, VG4, in addition to six auricular points unilaterally [Os sacrum (38), Parasympathicus (51), Nervus ischiadicus (52), Lumbossacrum (54), Shenmen (55), Kidney (95)]. The association of FT plus acupuncture (AG) showed superiority over the performance of isolated FT (CG) in twelve weeks, being that the last day of treatment on the pain scores (VAS 0-10) with AG-CG = -1.7 (CI 95% -2.71 to -0.62, $p < 0.000$), and function (PDI: 0-70): AG-CG = -11.3 (CI 95% -17.01 to -5.44, $p < 0.000$) in twelve weeks in favour of group FT plus acupuncture. Only function benefit was sustained in a nine-month follow-up, being that after treatment with PDI scale values of -6.8 (-12.57 to -0.96) $p < 0.016$ in nine months in favour of the group AG[68] **(B)**.

Actual acupuncture versus sham acupuncture

There is still controversy between the effectiveness of actual acupuncture, i.e., the deeper insertion in acupoints compared to sham acupuncture, i.e., the superficial insertion in sites far from the acupoints. It was observed that there are a few papers showing benefit of actual acupuncture[67,69] **(A)** and others that show equivalence between the two techniques[68,70] **(A,B)**. Despite that, it was proven that *sham* acupuncture with superficial insertion is not an inert procedure.

Study conducted by Brinkhaus et col. in 2006 involving 298 participants showed there was no benefit in the application of deep acupuncture compared to superficial acupuncture, subcutaneous, in acupuncture points routinely used in chronic lumbar pain, compared with subcutaneous acupuncture in eight, twenty-six and fifty-two weeks after treatment[70] **(A)**. There were twelve sessions, over eight weeks, with thirty minutes each, with the use of a minimum of four bilateral points, eight needles, which should be part of the following pool: BL 20 to 34, BL 50 to 54, GB 30, DM 3 to 5, with at least two points at a distance, among them SI3, B40, BL60, BL62, KI3, KI7, GB31, GB34, DM14, and DM20. In the subcutaneous acupuncture group were used six out of ten points, not acupoints, previously stipulated. This lack of significance was maintained also at the twenty-sixth and fiftieth weeks[70] **(A)**.

There was benefit in the application of acupuncture with intramuscular insertion compared to the subcutaneous insertion technique in the treatment of lumbar pain[69] **(A)**. The points used were Extra 19, VG6, GB34, BL54, BL62, plus four *ashipoints* with needle stimulation, i.e., rotation from one side to the other at 2 Hz for twenty seconds in the first minute and every five minutes until the end of session with duration of twenty minutes and in total eight sessions per month: Deep greater superficial, however with no statistical significance. Within three months: Deep greater superficial with significant difference after three months of treatment. Group acupuncture reached 7.5 (± 12.94) by the end whereas superficial 18 (± 17.16) as final *McGill Pain Questionaire* score[69] **(A)**.

Another study involving 186 participants showed there was benefit in the use of actual acupuncture plus routine orthopedic care such as physical therapy, physical exercises, heat irradiation, spinal schools, and mud packs in comparison with superficial

acupuncture plus routine orthopedic care ROC in three months after treatment[67] **(A)**. With the application of acupuncture in twelve sessions and three times a week frequency points: B23, B25, GB30, B40, B60, VB34 plus four *AhShi* points in the lumbar region and also moderate to strong manipulation with *DeQi* and with duration of thirty minutes per session, the results were the following: Success rates (reduction ≥ 50% in VAS scale "0-100" three months after the last treatment) were of 67% (CI 95%: 62-88%) with acupuncture and 29% (CI 95%: 16-46%) with *sham* acupuncture. Results between verum and sham significant with $p < 0.001$. Right after treatment the group that had acupuncture had 65% of success (CI 95%: 51-77%), whereas the sham group obtained 34% (CI 95%: 22-49%) of success. Significant results between verum and sham on the third month with $p < 0.02$[67] **(A)**.

There was no benefit in the application of actual acupuncture in comparison with sham acupuncture, superficial, after nine months of treatment of chronic lumbar pain[68] **(B)**.

Actual acupuncture versus placebo procedure versus TENS

By pondering the difference in quality present between two studies of this document it is noted that it can be affirmed that acupuncture has greater effectiveness compared to TENS and placebo, that is, there is higher quality[71] **(A)** and, by the other, that it is not affirmed[72] **(B)**.

Study conducted with acupuncture or electroacupuncture compared to TENS and placebo (inert), aiming the treatment of non-specific mechanical lumbar pain, showed beneficial result in the treatment. This study had fifty patients distributed in three groups, two involving acupuncture and one, solely, application of inert TENS, and all three groups had eight weekly sessions of treatment. The group with acupuncture used fourteen points per session, among those should be present: BL24, BL25, BL26, BL40, BL57, BL60, LI4, LI11, *Ex Jiaji*, with twenty minutes per session and needle manipulation with *DeQi* evocation three times during each session. On the other group the same technique was used and the same points with electroacupuncture, however with current flow 2-15 Hz with 2.5 second cycles in four needles, one pair on each side, also during twenty minutes. After one, three and six months from the last treatment it was observed a greater benefit in the groups that involved acupuncture in comparison with TENS and placebo with 13%, 23.5% and 38.5% improvement on the VAS scale (0-100) for the acupuncture group versus a worsening of 28%, 24% and 16% on the same scale for the TENS group and placebo, respectively, in the first, third and sixth months after the last treatment ($p < 0.000$, $p < 0.001$ and $p < 0.001$)[71] **(A)**.

Study of lower quality, with forty-six patients, showed that there was no statistically significant difference between the application of acupuncture in comparison to a TENS placebo procedure[72]. There were six weekly sessions for both groups with duration of thirty minutes each. The acupuncture group used eleven needles (0,3 x 50 mm) per session on the following points: BL23, BL25, GB30, BL40, KI3, GV4, with *DeQi* evocation. These needles were manipulated to maintain the *DeQi* three times in each session every ten minutes. The TENS group received inert electrodes in the lumbar region. There was no significance between the groups within four weeks and six months after treatment[72] **(B)**.

Simulated acupuncture versus actual acupuncture

There was no benefit between the application of actual acupuncture compared to simulated acupuncture, no insertion, only skin stimulation, in patients with chronic lumbar pain[73] **(A)**. Applied individualized acp (patient in prone, with no fixed measure of quantity of points, manipulation and depth). Standard acupuncture: BL40, DM3, localized *Ahshi*, BL23, KI3 for twenty minutes with rotational stimulation of the needle in ten and twenty minutes and acupuncture simulation with no needle insertion. Ten sessions twice a week for three weeks occurred and, later, once a week for four weeks. There was no statistically significant difference between the acupuncture groups, however, there is difference between these groups and the usual care group[73] **(A)**.

Acupuncture versus massage

Acupuncture showed to be inferior to massage in the treatment of chronic non-specific lumbar pain with the application of ten weekly therapy sessions in the parameters of pain and dysfunction. This benefit was maintained from the completion of treatment up to one year follow-up[74] **(B)**. In study involving 262 participants, the comparison between massage performed by twelve therapists with free technique (swedish 71%, movement reeducation 70%, deep-tissue 65%, wet heat or cold 51%, trigger-point or pressure 48% and neuromuscular 45%) in comparison with acupuncture also with free technique among acupuncturists (TCM, needle manipulation, moxa), with ten weekly sessions, massage showed to be superior to acupuncture by the end of treatment in the dysfunction score (modified RMDQ 0-23) by the end of ten weeks, (6,3 vs. 7.9, $p < 0.01$). After one year of follow-up, and by the end of the last treatment, massage was still superior to acupuncture in the dysfunction scale (6.29 vs. 8.21; $p < 0.05$) and, also, was better in the symptom scale (VAS 0-100) than acupuncture (3.08 vs. 4.74; $p < 0.002$)[74] **(B)**.

Acupuncture versus anesthetic injection

There is greater benefit in the application of acupuncture in comparison with the use of topic anesthetic in greater pain to palpation points in the treatment of chronic lumbar pain[75] **(B)**. With the use of two to five points in bird-biting technique at one cycle per second and for twenty second on the sites of greater pain to palpation in the lumbar spine with needle insertion depth of ten to twenty mm and application in four weekly sessions with 40 mm x 0.18 mm needles there was benefit from acupuncture in comparison with the application of topic anesthetic 5 mg distributed over the same points and at the same insertion depth. Reduction in VAS scale of 49.4 ± 17.0 (group acupuncture) versus 19.5 ± 26.8 (group anesthetic) after two weeks and 51.8 ± 15.8 (group acupuncture) versus 22.1 ± 28.8 (group anesthetic) after four weeks of treatment with statistical significance[75] **(B)**.

Acupuncture and adverse effects

Minimal adverse effects were described on all papers, the most common being transitory pain on the needle insertion site, local hematoma, small localized swelling, and transitory bleeding.

No severe adverse effects were found in any of the studies analyzed.

Recommendation

There are insufficient good quality studies in order to formulate strong evidence regarding the use of acupuncture in the treatment of chronic non-specific mechanical lumbar pain.

The application of acupuncture combined with other conservative therapies such as physical therapy, NSAID, anagesia, heat

application, self-care, and postural education is more beneficial than the application of the same therapies isolatedly, for the treatment of chronic non-specific mechanical lumbar pain [66,68] **(B)**.

There is still controversy between the effectiveness of actual acupuncture (deeper insertion in acupoints) compared to *sham* acupuncture (superficial insertion on sites at a distance from acupoints) in non-specific lumbar pain. There are studies showing benefit from actual acupuncture[67,69] **(A)**, and others show the equivalence between the two techniques[68,70] **(A,B)**. However, it was proven that sham acupuncture with superficial insertion is not an inert procedure. It was also seen, in one study, that there was no benefit between the application of actual acupuncture compared to simulated acupuncture, no insertion, only skin stimulation, in patients with chronic lumbar pain[73] **(A)**.

We affirm that acupuncture has greater effectiveness compared to TENS placebo based in study of higher quality[71] **(A)**, even though another study does not confirm such affirmation[72] **(B)**, pondering for that effect the difference in quality between the studies.

Acupuncture showed to be inferior to massage in the treatment of chronic non-specific lumbar pain with the application of ten weekly therapy sessions in the parameters of pain and dysfunction. This benefit was maintained from the completion of treatment up to one year follow-up[74] **(B)**.

There is greater benefit in the application of acupuncture in comparison with the use of topic anesthetic in greater pain to palpation points in the treatment of chronic lumbar pain[75] **(B)**.

Prevention of Pain

10. Does individual ergonomy orientation serve as pain recurrence prevention?

The low quantity of available studies that discuss the ergonomy issue regarding recurrence of chronic non-specific lumbar pain prevention, makes conclusive evidence impossible regarding this type of intervention[76,77] **(B)**.

When it is compared to other types of intervention, such as individual physical therapy and spinal manipulation, an intervention program composed of ergonomy and exercises performed during fifteen hours, five days a week, does not show superiority regarding functional disability and pain. The program that consists of educational sessions about daily life ergonomic aspects, either at home or in other places, showed worse results regarding these variables compared to the manipulation group[76] **(B)**.

When used as a technique to verify lumbar pain recurrence, ergonomy does not show any effect[77] **(B)**.

The ergonomic intervention program comprised of instructions about actions to reduce load to the spine, decrease asymmetries, and instructions on how to reduce unexpected loads imposed by the work of nursing staff, did not show beneficial effects in the prevention of chronic non-specific lumbar pain[77] **(B)**.

Recommendation

There are no evidences to define ergonomy as a beneficial intervention regarding recurrence prevention and reduction of chronic non-specific lumbar pain[77] **(B)**.

11. Does sustaining oriented aerobic physical exercise serve as pain recurrence prevention?

It is observed that studies regarding patients that participated in an exercise program report gaining a few benefits. However, these benefits and their relevance in overall health condition need better investigation, since there are several confusing variables in these studies[78] **(A)**.

The low quantity of available studies that discuss whether sustaining oriented light exercise prevents pain recurrence, combined with the methodological limitations of the papers found, makes any conclusive evidence impossible both regarding the application of this type of treatment, and regarding cost versus effectiveness of such interventions in non-specific lumbar pain[79-82] **(A)**.

Exercise, regardless of duration and intensity, is most associated with improvement of conditioning and wellness of individuals, regarding psychological aspects such as humour and self-confidence for the development of their daily tasks[83-86] **(A)**.

However, there are a few studies about perception on patients that perform supervised exercises between one and ten years, that reveal that supervised physical training twice a week, with one hour of static and dynamic exercises over, at least, three consecutive weeks, contributes to the performance of functional capacity and improvement in pain recurrence[87-90] **(A,B)**.

Improvement in pain was identified in one supervised exercise program, where in the first phase, first to fourth weeks, therapies were performed twice a week, each session with duration of at least one hour, composed of static and dynamic exercises using, mainly, pulleys and small weights. According to the individual's tolerance, weight, number of repetitions, speed and amplitude of movement would be adjusted and, gradually, increased during the first phase. In the next phase, fifth to eighth weeks, they were performed three times a week, with duration of one hour each, being that the exercises would be repeated at least two to fifteen times each. The third phase, nine to twelve weeks, was composed of training two times a week with duration of one hour each. Each session started with a low-impact aerobic warm-up followed by stretching[87] **(A)**.

Recommendation

There are no evidences to define physical exercise as pain a recurrence prevention tool. The studies indicated that regardless of exercise type, time, duration, or intensity, the benefit of prevention of a renewed pain crisis cannot be affirmed[87-90] **(A,B)**.

Economical Assessment

12. What is the cost-effectiveness of acupuncture for chronic lumbar pain?

Few studies were found that evaluated the cost-effectiveness of acupuncture for chronic lumbar pain. Among the studies found, we could see that the assessment was performed by means of incremental cost-effectiveness by QALY gain (calculated the number of quality-adjusted life years (QALYs).

In the United Kingdom, for instance, a threshold of £ 30.000 (thirty thousand pounds) per QALY is used for the decisions regarding adoption of new technologies. In Germany and in Brazil, there is no definition of such a threshold[91] **(B)**.

One study conducted in Germany defined, hypothetically, £ 50.000 (fifty thousand euros) per QALY. Both pain and quality of life were evaluated at the start, and after three and six months. This study had 11.630 patients (average age = 52.9 years (standard deviation 13.7); female 59%), 1.549 were randomized in the acupuncture group and 1.544 in the control group; 8.537 were included in the non-randomized acupuncture group. At three months, it was

identified improvement in function of 12.1 (standard error (SE), 0.4) to 74.5 (SE, 0.4) points in the acupuncture group and of 2.7 (SE, 0.4) to 65.1 (SE, 0.4) points between the controls (difference equal to 9.4 points (confidence interval of 95%, 8,3 to 10.5, $p < 0.001$, CER 0.631, EER 0.426, RRR 32%, ARR 0.205, NNT 5). Non-randomized patients presented more severe symptoms and showed improvement in function similar to those observed in randomized patients. The incremental cost-effectiveness relation was 10,526 Euros per quality-adjusted life years. Acupuncture plus routine care were associated with clinical improvement in these patients being, relatively, profitable[91] **(B)**.

Total costs were included during the three months after randomization, including those costs not related to chronic lumbar pain, and the diagnostic costs specific to chronic lumbar pain and related diseases. The direct costs related to health included were medical appointments, hospital internments, medications, acupuncture, treatment, and number of medical leaves[91] (B).

The acupuncture service was considered profitable in twenty-four months, the estimated quality-adjusted cost (QALY) was £ 4.241 (Pounds), (confidence interval of 95% - 191 £ to £ 28.026), using the SF-6D scoring algorithm based on the answers to the SF-36 questionnaire and £ 3.598 (Pounds), (confidence interval of 95% - £ 189 to £ 22,035), using the health EQ-5D[92] **(B)**.

Costs were higher with the use of acupuncture, average of eight to ten sessions, 9.6 needles per treatment and interval of six to twelve, time of treatment from ten to thirty minutes, variation of 177 different acupoints, used both bilaterally and unilaterally. The needles were 25 mm or 40 mm long with 0.20 mm to 0.30 mm diameter. The points of bladder and gall bladder channels were very much used, 38.4% and 14.9% respectively, as well as points such as BL-23 (22.9%); the selected points were many times a combination of site such as BL-23, BL-26, BL-53, BL-54, and GB-30, as well as minor lumbar points and distal points such as BL-40, BL-60, GB-34, and GB-40; medical appointments, pain medications, total per capita of £ 471.10 than in usual treatment, pain medications, physical therapy, exercises, amount of (£ 332.24), however, the quality of life of individuals that use acupuncture as well as the social cost such as absenteeism rate is higher for individuals that do not use acupuncture (acupuncture (£ 2.135,39), whereas without acupuncture (£ 2.469.09)[92] **(B)**.

Recommendation

Although acupuncture is associated with cost raise in the treatment of non-specific lumbar pain, its use is recommended for the treatment of non-specific lumbar pain, for ten sessions twice a week, for the reduction of social cost to the individual, improving quality of life, and reducing absenteeism[92] **(B)**.

Acupuncture plus routine care, resulted in a clinically relevant benefit and is cost-effective among patients with chronic lumbar pain of the practices of primary attention in Germany. Therefore, acupuncture should be considered as a viable option for the management of patients with chronic lumbar pain[91] **(B)**.

REFERENCES

1. Ford JJ, Story I, O'Sullivan P, McMeeken JM. Classification systems for low back pain: a review of the methodology for development and validation. Phys Ther Rev. 2007;12(1):33-42.
2. Andrade SC, Araujo AGR, Vilar MJP. "Escola de coluna": revisão histórica e sua aplicação na lombalgia crônica. Rev Bras Reumatol. 2005;45(4):224-28.
3. Lin CC, Hass M, Maher CGM, Machado LACM, Tulder MWV. Cost-effectiveness of guideline-endorsed treatments for low back pain: a systematic review. Eur Spine J. 2011;20:1024-38.
4. Hickey RF. Chronic low back pain: a comparison of diflunisal with paracetamol. N Z Med J. 1982;95(707):312-4.
5. Peloso PM, Fortin L, Beaulieu A, Kamin M, Rosenthal N. Protocol TRP-CAN-1 Study Group. Analgesic efficacy and safety of tramadol/acetaminophen combination tablets (Ultracet) in treatment of chronic low back pain: a multicenter, outpatient, randomized, double blind, placebo controlled trial. J Rheumatol. 2004;31(12):2454-63.
6. Ruoff GE, Rosenthal N, Jordan D, Karim R, Kamin M; Protocol CAPSS-112 Study Group. Tramadol/acetaminophen combination tablets for the treatment of chronic lower back pain: a multicenter, randomized, double-blind, placebo-controlled outpatient study. Clin Ther. 2003;25(4):1123-41.
7. Videman T, Osterman K. Double-blind parallel study of piroxicam versus indomethacin in the treatment of low back pain. Ann Clin Res. 1984;16(3):156-60.
8. Chang ST, Chen LC, Chang CC, Chu HY, Tsai KC. Effects of piroxicam-beta-cyclodextrin sachets on abnormal postural sway in patients with chronic low back pain. J Clin Pharm Ther. 2008;33(5):495-506.
9. Zerbini C, Ozturk ZE, Grifka J, Maini M, Nilganuwong S, Morales R, et al. Efficacy of etoricoxib 60 mg/day and diclofenac 150 mg/day in reduction of pain and disability in patients with chronic low back pain: results of a 4-week, multinational, randomized, double-blind study. Curr Med Res Opin. 2005;21(12):2037-49.
10. Berry H, Bloom B, Hamilton EB, Swinson DR. Naproxen sodium, diflunisal, and placebo in the treatment of chronic back pain. Ann Rheum Dis. 1982;41(2):129-32.
11. Hickey RF. Chronic low back pain: a comparison of diflunisal with paracetamol. N Z Med J. 1982; 95(707):312-4.
12. Veenema KR, Leahey N, Schneider S. Ketorolac versus meperidine: ED treatment of severe musculoskeletal low back pain. Am J Emerg Med. 2000;18(4):404-7.
13. Ilic KV, Sefik-Bukilica M, Jankovic S, Vujasinovic-Stupar N. Efficacy and safety of two generic copies of nimesulide in patients with low back pain or knee osteoarthritis. Reumatismo. 2009;61(1):27-33.
14. Birbara CA, Puopolo AD, Munoz DR, Sheldon EA, Mangione A, Bohidar NR, et al. Treatment of chronic low back pain with etoricoxib, a new cyclo-oxygenase-2 selective inhibitor: improvement in pain and disability-a randomized, placebo-controlled, 3-month trial. J Pain. 2003;4(6):307-15.
15. Pallay RM, Seger W, Adler JL, Ettlinger RE, Quaidoo EA, Lipetz R, et al. Etoricoxib reduced pain and disability and improved quality of life in patients with chronic low back pain: a 3 month, randomized, controlled trial. Scand J Rheumatol. 2004;33(4):257-66.
16. Katz N, Ju WD, Krupa DA, Sperling RS, Bozalis Rodgers D, Gertz BJ, et al. Efficacy and safety of rofecoxib in patients with chronic low back pain: results from two 4-week, randomized, placebo-controlled, parallel-group, double-blind trials. Spine (Phila Pa 1976). 2003;28(9):851-8.
17. Katz N, Rodgers DB, Krupa D, Reicin A. Onset of pain relief with rofecoxib in chronic low back pain: results of two four-week, randomized, placebo-controlled trials. Curr Med Res Opin. 2004;20(5):651-8.
18. Coats TL, Borenstein DG, Nangia NK, Brown MT. Effects of valdecoxib in the treatment of chronic low back pain: results of a randomized, placebo-controlled trial. Clin Ther. 2004;26(8):1249-60.
19. O'Donnell JB, Ekman EF, Spalding WM, Bhadra P, McCabe D, Berger MF. The effectiveness of a weak opioid medication versus a cyclo-oxygenase-2 (COX-2) selective non-steroidal anti-inflammatory drug in treating flare-up of chronic low-back pain: results from two randomized, double-blind, 6-week studies. J Int Med Res. 2009;37(6):1789-802.
20. Romanò CL, Romanò D, Bonora C, Mineo G. Pregabalin, celecoxib, and their combination for treatment of chronic low-back pain. J Orthop Traumatol. 2009;10(4):185-91.
21. Gonzalez Maza C, Moscoso López L, Ramírez Elizalde G, Abdo Andrade A. Multimodal treatment of chronic unspecific low back pain. Acta Ortop Mex. 2010;24(2):88-94.
22. Setakis E, Leufkens HG, van Staa TP. Changes in the characteristics of patients prescribed selective cyclooxygenase 2 inhibitors after the 2004 withdrawal of rofecoxib. Arthritis Rheum. 2008;59(8):1105-11.
23. Solomon DH, Glynn RJ, Rothman KJ, Schneeweiss S, Setoguchi S, Mogun H, et al. Subgroup analyses to determine cardiovascular risk associated with nonsteroidal antiinflammatory drugs and coxibs in specific patient groups. Arthritis Rheum. 2008;59(8):1097-104.
24. Ruoff GE, Rosenthal N, Jordan D, Karim R, Kamin M. Tramadol/acetaminophen combination tablets for the treatment of chronic lower back pain: a multicenter, randomized, double-blind, placebo-controlled outpatient study. Clin Ther. 2003;25(4):1123-41.

25. Perrot S, Krause D, Crozes P, Naïm C. Efficacy and tolerability of paracetamol/tramadol (325 mg/37.5 mg) combination treatment compared with tramadol (50 mg) monotherapy in patients with subacute low back pain: a multicenter, randomized, double-blind, parallel-group, 10-day treatment study. Clin Ther. 2006; 28(10):1592-606.
26. Gordon A, Callaghan D, Spink D, Cloutier C, Dzongowski P, O'Mahony W, et al. A Buprenorphine transdermal system in adults with chronic low back pain: a randomized, double-blind, placebo-controlled crossover study, followed by an open-label extension phase. Clin Ther. 2010;32(5):844-60.
27. Hale M, Khan A, Kutch M, Li S. Once-daily OROS hydromorphone ER compared with placebo in opioid-tolerant patients with chronic low back pain. Curr Med Res Opin. 2010;26(6):1505-18.
28. Hale ME, Ahdieh H, Ma T, Rauck R Efficacy and safety of OPANA ER (oxymorphone extended release) for relief of moderate to severe chronic low back pain in opioid-experienced patients: a 12-week, randomized, double-blind, placebo-controlled study. J Pain. 2007;8(2):175-84.
29. Hale ME, Dvergsten C, Gimbel J. Efficacy and safety of oxymorphone extended release in chronic low back pain: results of a randomized, double-blind, placebo- and active-controlled phase III study. J Pain. 2005;6(1):21-8.
30. O'Donnell JB, Ekman EF, Spalding WM, Bhadra P, McCabe D, Berger MF. The effectiveness of a weak opioid medication versus a cyclo-oxygenase-2 (COX-2) selective non-steroidal anti-inflammatory drug in treating flare-up of chronic low-back pain: results from two randomized, double-blind, 6-week studies". J Int Med Res. 2009;37(6):1789-802.
31. Jamison RN, Raymond SA, Slawsby EA, Nedeljkovic SS, Katz NP. Opioid therapy for chronic noncancer back pain. A randomized prospective study. Spine (Phila Pa 1976). 1998;23(23):2591-600.
32. Skljarevski V, Zhang S, Desaiah D, Alaka KJ, Palacios S, Miazgowski T, et al. Duloxetine versus placebo in patients with chronic low back pain: a 12-week, fixed-dose, randomized, double-blind trial. J Pain. 2010;11(12):1282-90.
33. Skljarevski V, Desaiah D, Liu-Seifert H, Zhang Q, Chappell AS, Detke MJ, et al. Efficacy and safety of duloxetine in patients with chronic low back pain. Spine (Phila Pa 1976). 2010;35(13):E578-85.
34. Skljarevski V, Ossanna M, Liu-Seifert H, Zhang Q, Chappell A, Iyengar S, et al. A double-blind, randomized trial of duloxetine versus placebo in the management of chronic low back pain. Eur J Neurol. 2009;16(9):1041-8.
35. Mazza M, Mazza O, Pazzaglia C, Padua L, Mazza S. Escitalopram 20 mg versus duloxetine 60 mg for the treatment of chronic low back pain. Expert Opin Pharmacother. 2010;11(7):1049-52.
36. Katz J, Pennella-Vaughan J, Hetzel RD, Kanazi GE, Dworkin RH. A randomized, placebo-controlled trial of bupropion sustained release in chronic low back pain. J Pain. 2005;6(10):656-61.
37. Atkinson JH, Slater MA, Williams RA, Zisook S, Patterson TL, Grant I, et al. A placebo-controlled randomized clinical trial of nortriptyline for chronic low back pain. Pain. 1998;76(3):287-96.
38. Atkinson JH, Slater MA, Wahlgren DR, Williams RA, Zisook S, Pruitt SD, et al. Effects of noradrenergic and serotonergic antidepressants on chronic low back pain intensity. Pain. 1999;83(2):137-45.
39. See S, Ginzburg R. Choosing a skeletal muscle relaxant. Am Fam Physician. 2008;78(3):365-70.
40. Van Tulder MW, Touray T, Furlan AD, Solway S, Bouter LM. Muscle relaxants for nonspecific low back pain: a systematic review within the framework of the cochrane collaboration. Spine (Phila Pa 1976). 2003; 28(17):1978-92.
41. Schnitzer TJ, Ferraro A, Dip.rer.pol EH, Kong SX.A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain.J Pain Symptom Manage. 2004;28(1):72-95.
42. Chou R, Peterson K, Helfand M. Comparative efficacy and safety of skeletal muscle relaxants for spasticity and musculoskeletal conditions: a systematic review. J Pain Symptom Manage. 2004; 28(2):140-75.
43. Greve JM. Tratado de medicina de reabilitação. São Paulo: Roca; 2007.
44. Durmus D, Durmaz Y, Canturk F. Effects of therapeutic ultrasound and electrical stimulation program on pain, trunk muscle strength, disability, walking performance, quality of life, and depression in patients with low back pain: a randomized-controlled trial. Clin Rheumatol. 2008;27:873-81.
45. Koldaş Doğan S, Sonel Tur B, Kurtaiş Y, Atay MB. Comparison of three different approaches in the treatment of chronic low back pain. Clin Rheumatol. 2008;27:873-81.
46. Kulisch A, Bender T, Németh A, Szekeres L. Effect of thermal water and adjunctive electrotherapy on chronic low back pain: a double-blind, randomized, follow-up study. J Rehabil Med. 2009;41:73-9.
47. Ahmed MS, Shakoor MA, Khan AA. Evaluation of the effects of shortwave diathermy in patients with chronic low back pain. Bangladesh Med Res Counc Bull. 2009;35:18-20.
48. Weiner DK, Rudy TE, Glick RM, Boston JR, Lieber SJ, Morrow LA, et al. Efficacy of percutaneous electrical nerve stimulation forthe treatment of chronic low back pain in older adults. JAGS. 2003;51:599-608.
49. Hsieh RL, Lee WC. One-shot percutaneous electrical nerve stimulation vs. transcutaneous electrical nerve stimulation for low back pain. comparison of therapeutic effects. Am J Phys Med Rehabil. 2002;81(11):838-43.
50. Durmus D, Akyol Y, Alayli G, Tander B, Zahiroglu Y, Canturk F. Efects of electrical stimulation program on trunk muscle strength, functional capacity, quality of life, and depression in the patients with low back pain: a randomized controlled trial. Rheumatol Int. 2009;29:947.
51. Weiner DK, Perera S, Rudy TE, Glick RM, Shenoy S, Delitto A. efficacy of percutaneous electrical nerve stimulation and therapeutic exercise for older adults with chronic low back pain: a randomized controlled trial. Pain. 2008;140(2):344-57.
52. Durmus D, Durmaz Y, Canturk F. Effects of therapeutic ultrasound and electrical stimulation program on pain, trunk muscle strength, disability, walking performance, quality of life, and depression in patients with low back pain: a randomized-controlled trial. Rheumatol Int. 2010;30(7):901-10.
53. Koldaş Doğan S, Sonel Tur B, Kurtaiş Y, Atay MB. Comparison of three different approaches in the treatment of chronic low back pain. Clin Rheumatol. 2008;27(7):873-81.
54. Melzack R, Vetere P, Finch L. Transcutaneous electrical nerve stimulation for low back pain. A comparison of TENS and massage for pain and range of motion. Phys Ther. 1983;63(4):489-93.
55. Yokoyama M, Sun X, Oku S, Taga N, Sato K, Mizobuchi S, et al. Comparison of percutaneous electrical nerve stimulation with transcutaneous electrical nerve stimulation for long-term pain relief in patients with chronic low back pain. Anesth Analg. 2004;98(6):1552-6.
56. Durmus D, Alayli G, Canturk F. Effects of quadriceps electrical stimulation program on clinical parameters in the patients with knee osteoarthritis. Clin Rheumatol. 2007;26:674-8.
57. Kahanovitz N, Nordin M, Verderame R. Normal trunk muscle strength and endurance in women and the effects of exercises and electrical stimulation. Spine. 1987;12:112-8.
58. Ghoname EIA, Craig WF, White PF. Percuteneous electrical nerve stimulation for low back pain. JAMA. 1999; 281:818-23.
59. Durmus D, Akyol Y, Alayli G, Tander B, Zahiroglu Y, Canturk F. Effects of electrical stimulation program on trunk muscle strength, functional capacity, quality of life, and depression in the patients with low back pain: a randomized controlled trial. Rheumatol Int. 2009;29(8):947-54.
60. Kuukkanen T, Mälkiä E, Kautiainen H, Pohjolainen H. Effectiveness of a home exercise programme in low back pain: a randomized five-year follow-up study. Physiother Res Int. 2007;12(4):213-24.
61. Andrade SC, Araújo AGR, Vilar MJ. Escola de coluna para pacientes com lombalgia crônica inespecífica: benefícios da associação de exercícios e educação ao paciente. Acta Reumatol Port. 2008;33:443-50.
62. Van der Roer N, Tulder M, Barendse J, Knol D, van Mechelen W, Vet H. Intensive group training protocol versus guideline physiotherapy for patients with chronic low back pain: a randomized controlled Trial. Eur Spine J. 2008;17:1193-1200.
63. Ferreira ML, Ferreira PH, Herbert RD, Hodges PW, Jennings M, Maher CG, et al. Comparison of general exercise, motor control exercise and spinal manipulative therapy for chronic low back pain: a randomized Trial. Pain. 2007;131:31-7.
64. Kell RT, Asmundson GJG. A comparison of two forms of periodized exercise rehabilitation programs in the management of chronic nonspecific low-back pain. J Strength Cond Res. 2009; 23(2):513-523.
65. Lewis JS, Hewitt JS, Billington L, Cole S, Byng J, Karayiannis S. A randomized clinical trial comparing two physiotherapy interventions for chronic low back pain. Spine (Phila Pa 1976). 2005;30(7):711-21.
66. Meng CF, Wang D, Ngeow J, Lao L, Peterson M, Paget S. Acupuncture for chronic low back pain in older patients: a randomized, controlled trial. Rheumatology (Oxford). 2003;42(12):1508-17.
67. Molsberger AF, Mau J, Pawelec DB, Winkler J. Does acupuncture improve the orthopedic management of chronic low back pain - a randomized, blinded, controlled trial with 3 months follow up. Pain. 2002;99(3):579-87.
68. Leibing E, Leonhardt U, Köster G, Goerlitz A, Rosenfeldt JA, Hilgers R, et al. Acupuncture treatment of chronic low-back pain - a randomized, blinded, placebo-controlled trial with 9-month follow-up. Pain. 2002;96(1-2):189-96.

69. Ceccherelli F, Rigoni MT, Gagliardi G, Ruzzante L. Comparison of superficial and deep acupuncture in the treatment of lumbar myofascial pain: a double-blind randomized controlled study. Clin J Pain. 2002;18(3):149-53.
70. Brinkhaus B, Witt CM, Jena S, Linde K, Streng A, Wagenpfeil S, et al. Acupuncture in patients with chronic low back pain: a randomized controlled trial. Arch Intern Med. 2006;166(4):450-7.
71. Carlsson CP, Sjölund BH. Acupuncture for chronic low back pain: a randomized placebo-controlled study with long-term follow-up. Clin J Pain. 2001;17(4):296-305.
72. Kerr DP, Walsh DM, Baxter D. Acupuncture in the management of chronic low back pain: a blinded randomized controlled trial. Clin J Pain. 2003;19(6):364-70.
73. Cherkin DC, Sherman KJ, Avins AL, Erro JH, Ichikawa L, Barlow WE, et al. A randomized trial comparing acupuncture, simulated acupuncture, and usual care for chronic low back pain. Arch Intern Med. 2009;169(9):858-66.
74. Cherkin DC. Randomized trial comparing traditional Chinese medical acupuncture, therapeutic massage, and self-care education for chronic low back pain. Arch Intern Med. 2001;161(8):1081-8.
75. Inoue M, Hojo T, Nakajima M, Kitakoji H, Itoi M. Comparison of the effectiveness of acupuncture treatment and local anaesthetic injection for low back pain: a randomised controlled clinical trial. Acupunct Med. 2009;27(4):174-7.
76. Cecchi F, Molino-Lova R, Chiti M, Pasquini G, Don Carlo APF. Spinal manipulation compared with back school and with individually delivered physioteraphy for the treatment of chronic low back pain: a randomized trial with one-year follow-up. Clin Rheumatol. 2010;24:26-36.
77. Jense LD, Gonge H, Jørs E, Ryom P, Foldspang A, Christensen M, et al. Prevention of low back pain in female eldercare workers: randomized controlled work site trial. Spine. 2006; 31:1761-9.
78. Henchoz Y, de Goumoëns P, Norberg M, Paillex R, So AK. Role of physical exercise in low back pain rehabilitation: a randomized controlled trial of a three-month exercise program in patients who have completed multidisciplinary rehabilitation. Spine (Phila Pa 1976). 2010;35(12):1192-9.
79. Hagen EM, Ødelien KH, Lie SA, Eriksen HR. Adding a physical exercise programme to brief intervention for low back pain patients did not increase return to work. Scand J Public Health. 2010;38(7):731-8.
80. Kent P, Mjøsund HL, Petersen DH. Does targeting manual therapy and/or exercise improve patient outcomes in nonspecific low back pain? A systematic review. BMC Med. 2010;8:22.
81. Ben Salah Frih Z, Fendri Y, Jellad A, Boudoukhane S, Rejeb N. Efficacy and treatment compliance of a home-based rehabilitation programme for chronic low back pain: a randomized, controlled study. Ann Phys Rehabil Med. 2009;52(6):485-96.
82. Jones MA, Stratton G, Reilly T, Unnithan VB. Recurrent non-specific low-back pain in adolescents: the role of exercise. Ergonomics. 2007;50(10):1680-8.
83. Hurwitz EL, Morgenstern H, Chiao C. Effects of recreational physical activity and back exercises on low back pain and psychological distress: findings from the UCLA Low Back Pain Study. Am J Public Health. 2005;95(10):1817-24.
84. Koldaş Doğan S, Sonel Tur B, Kurtaiş Y, Atay MB. Comparison of three different approaches in the treatment of chronic low back pain. Clin Rheumatol. 2008;27(7):873-81.
85. Pillastrini P, Mugnai R, Bertozzi L, Costi S, Curti S, Mattioli S, et al. Effectiveness of an at-work exercise program in the prevention and management of neck and low back complaints in nursery school teachers. Ind Health. 2009;47(4):349-54.
86. Sculco AD, Paup DC, Fernhall B, Sculco MJ. Effects of aerobic exercise on low back pain patients in treatment. Spine J. 2001;1(2):95-101.
87. Maul I, Läubli T, Oliveri M, Krueger H. Long-term effects of supervised physical training in secondary prevention of low back pain. Eur Spine J. 2005;14(6):599-611.
88. Rasmussen-Barr E, Ang B, Arvidsson I, Nilsson-Wikmar L. Graded exercise for recurrent low-back pain: a randomized, controlled trial with 6-, 12-, and 36-month follow-ups. Spine (Phila Pa 1976). 2009;34(3):221-8.
89. Kuukkanen T, Mälkiä E, Kautiainen H, Pohjolainen T. Effectiveness of a home exercise programme in low back pain: a randomized five-year follow-up study. Physiother Res Int. 2007;12(4):213-24.
90. Frost H, Lamb SE, Klaber Moffett JA, Fairbank JC, Moser JS. A fitness programme for patients with chronic low back pain: 2-year follow-up of a randomised controlled trial. Pain. 1998;75(2-3):273-9.
91. Witt CM, Jena S, Selim D, Brinkhaus B, Reinhold T, Wruck K, et al. Pragmatic randomized trial evaluating the clinical and economic effectiveness of acupuncture for chronic low back pain. Am J Epidemiol. 2006;164(5):487-96.
92. Thomas KJ, MacPherson H, Ratcliffe J, Thorpe L, Brazier J, Campbell M, et al. Longer term clinical and economic benefits of offering acupuncture care to patients with chronic low back pain. Health Technol Assess. 2005;9(32):1-109.