

CLINICAL *PAPER*

22 aprile 2013

DIAMAGNETIC THERAPY INNOVATIVE PHYSICAL THERAPY FOR CONSERVATIVE TREATMENT OF CHRONIC LOW BACK PAIN

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Summary

In February 2011 to July 2011, it has been carried out a verification towards the effectiveness of Conservative Treatment Program for Chronic low back pain with CTU MEGA 18 Diamagnetic Pump featured by Magnetic Field with 2 Tesla intensity, hyper pulsed and low frequency at the PHYSIOTHERAPY CENTER CHIMERA of Arezzo. The results are very satisfying according to patients' subjective and objective assessment of conventional Scale Measurement from the therapies involved in the Center, reduction of consistent symptomatology at the end of Program and improvement and the consolidation of results assessed in the FOLLOW UP for 3, 6 and 9 months.

INTRODUCTION TO LOW BACK PAIN A COMMON PROBLEM

“Back pain” is one of frequent sources of General Practitioner cases which is slightly less than 20% of all rheumatism disease and the third reason after the hypertension and preventive medicine. Although the important pathologies can be the reason, in about 90% of cases is specified as benign and self limitation. The information given by the European Unity Agency for the safety and the health at work in 2012 indicate that the prevalence of low back pain in Italy is around 32%, close to the average level of European Union Countries which has 25%. Consequently, the low back pain in Industrial Countries is one of the pathology that takes majority in the sanitary costs and it causes the absence at work, this is the most frequent world’s orthopedic cases.

CLINICAL TRIAL

The social data analysis indicates 50% of Low Back Pain Symptom amongst the adults at working age range and about 20% must carry out specific medical care.

The back pain is the most frequent reason of disability amongst the person with the range of age inferior than 45 years old. As long as the job in our country continue to demand a high involvement of osteo articular apparatus, consulting taken place in General Practitioner will be as well continuous and as a consequence it follows the requests from Physical Medicine and Physiotherapy for rehabilitation treatments.

This Clinical Trial is designed to verify the efficiency of a new care program of treatment carried out with CTU MEGA 18 DIAMAGNETIC PUMP, technology featured by Magnetic Field with high intensity, hyper pulsed and at low frequency that reacts in biophysics and biochemistry of tissue resulting to a stable results on the symptomatology.

It is proposed in the term of Therapeutic Options which is actually present and that we can synthesize in:

- Pharmacology therapy which are certainly useful are constitute from paracetamol and of NSAIDs if the paracetamol is contra indicated or not effective. Other pharmacies do not demonstrate effectiveness as well as poli-pharmacological mixture.
- Non pharmacology therapy have more modest effectiveness and often at the short term.
- Amongst the physical therapy that has been exercised, they carry out as well analgesic current applications and treatments with Diathermy that proved to be very effective but obviously applicable only on the patients that able to access to the ambulatory.
- Even the delicate massage using eventually a rubefacient cream can create a certain releasing effect for the patients.
- Physical activity seems very useful to prevent the relapse but also for this aspect, it is necessary to have further research.
- Through the needles' system, it is possible to inject in the disc a mixture of oxygen and ozone with good results. You can carry out discolysis with Laser and therapy on the facet joints of radio-thermo ritzotomia with optimum results should you like to make a treatment without the needles. Recent statistic shows, however, a rare effectiveness of nucleus aspiration through endoscopic probe as well to the enzyme injection such as chymopapain.
- SURGICAL THERAPY is taken into consideration only in the case of radiculopathy signs and not before a conservative therapy period which varies from one to two years.
- In the ACUTE phase meanwhile waiting for the certainty of the real problem, the right therapy is symptomatic type. They used analgesic pharmacology, anti inflammation and the muscle relaxants.

In cases with lots of pain, it is prescribed the cortisone through the intra muscular.

- It is better indeed for the patient to bed rest for one or maximum two days with lying position on his side with a small pillow placed between the knees.

In particular sore case, we recommend the use of lumbar corset for a brief time and never in the evening.

- For CHRONIC back ache patients, they are taught to take care of his situation (Self-care Activities) with practicing some analgesic position such as the supine positions with flexed hips and knees with the legs resting on the piles of pillows (Fig 7). It is recommended and very useful to guide the patient at the beginning of the exercise and to let them know behaviors to be applied in daily activity to avoid the mechanical stress on the vertebrae, rebalance the muscles chain and to obtain a good proprioception, means the ability to feel the contraction of the muscle and the body position. There are countless method for the aforementioned method: The Mezieres, McKenzie, Global postural re-education and Feldenkrais method.

- Osteopathic treatments and traditional massage can be effective as long as it is carried out by the experts.

LOW BACK PAIN ETIOPATHOLOGY DIVERSIFIED

The general term of low back pain indicates the presence of pain at the lumbar that can eventually irradiate to the gluteus and the posterior part of the thigh (lumbar sciatica) or the anterior part (lumbar cruralgia). The contemporary presence of pain at lumbar and sacral is defined as lumbar cruralgia.

The lumbar is a most frequent condition and its frequency occurs when a person reach the age of 60 years and it hit 50% of the population.

Generally, it is consequences of the muscle skeleton alteration and rarely a sufferance of internal organs such as urinary, pancreas, abdominal aorta or the prostate.

When the problem is local, 85% of the origin cases is from the muscles, meanwhile 15% of them is related to column problem that can affect the amount of bone, ligaments or the inter vertebral disc.

The vertebral column or the spine is subdivided into 5 parts (cervical, dorsal, lumbar, sacral and coccygeal) (Fig 1) and it is shaped by the vertebral (Fig 2) that in the first 3 sections are separate from the fibro cartilaginous (Fig 3).

Several muscles and ligaments have their own solid structure. Observing from vertebral part (Fig 4), we can observe the inter vertebral disc that consists entirely from a nucleus pulposus and at the external part it is constituted from a fibrous ring. The disc acts as a cushion between the vertebra above and the one below, improving the congruency and therefore to stabilize the column.

Healthy discs, being well hydrated, allow a fluid movement of the spine and they maintain pervious of the lateral spaces of inter vertebral foramina (conjugation foramina) through those passages of direct nerves to the inferior articular. At the front, we have vertebral foro (Fig 2) that contents of spinal midollo. Various midollo foro above constitute the midollo channel. From this midollo come out the anterior and posterior nerve radix. After being through the conjugation foramina, they unite in a sole spinal nerve for the sensitive innervations and motoric.

The great importance are the anterior and posterior longitudinal ligaments that run the entire column and have the function of maintaining the vertebrae aligned, establishing the spine and preventing the injuries to the spine midollo.

FIG 1

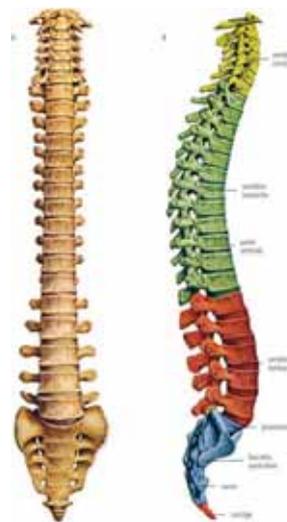


FIG 2

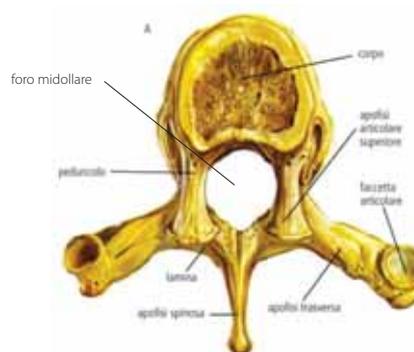


FIG 3

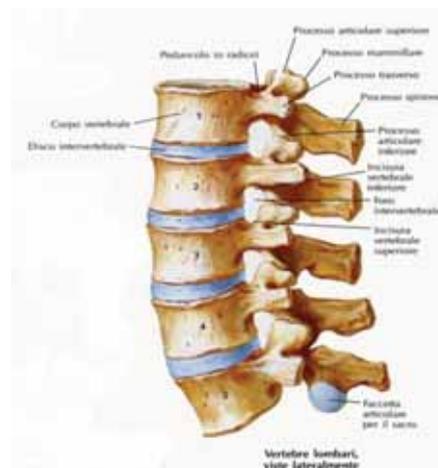
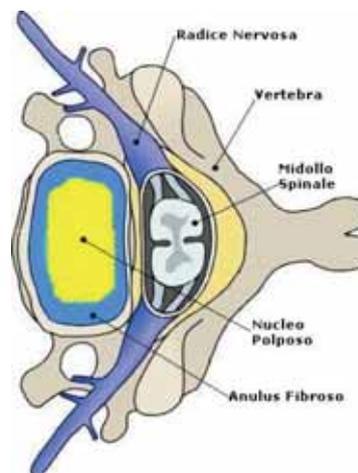


FIG 4



THE CAUSE OF SKELETAL MUSCLE THAT CAN PROVOKE A LOW BACK PAIN ARE MANY:

- Congenital deformities of the column as spondylolisthesis is the vertebra slipping on the other or the diameter reduction of the vertebral channel.
- Vertebral degenerative processes such as arthritis with possible formation of osteophytic protrusions or osteoporosis.
- Inflammation processes such as spondylitis, rheumatoid arthritis
- Contracture of some muscles such as the iliopsoas
- Infective processes such as TBC, herpes zoster, meningitis
- Primary tumors or metastases localized to the column
- Connective disease, fibromyalgia
- Alteration of column ligaments
- Traumas or vertebral fractures
- Defense muscle contracture, alteration of the posture
- Pregnancy, due to the weight increase and variation of physiology of lumbar curve of the column and of the pelvis
- Outcomes of the surgery interventions for hernia disc (low back pain can be presented in 10 – 15% of cases)
- Psychoneurotic problems
- Hernia disc

It is about the disc protrusion (bulging) when the nucleus determines through the fibrotic ring but it does not exceed a swelling of fibrotic ring without damaging it.

When the nucleus goes through the fibrotic ring but it does not go through the posterior longitudinal (starts in the anterior part of the vertebral channel), it is called contained hernia; if it goes through the extruded hernia.

When the hernia comes off of the disc and it can move to the other part or at the low part of the vertebral channel, it is called migrant hernia.

As you can observe from Fig 5, when the hernia at the posterior part, it tends to squeeze the sheaths that cover the nerve midollo (5) if it present at the posterior and lateral part, it squeeze the nerve root (2).

Therefore it is not the hernia itself that make the pain but the eventual compression on the surrounding structure comes from the edema and extravasation hematic when it forms hernia tissue; it explains the casual respond of asymptomatic hernia in so many subjects.

Predisposing factors of lumbar are a form of poor physical condition, an excessive physical exercise with repeating weight lifting following flattening and rotating the torso, overweight, sitting work, stress and the depression, or the

lack of knowledge of ergonomic regulation such as flex forward instead of bending the knees or use a very hard mattress or very soft. Often even the problems at the hips cause the reflection low back pain.

LOW BACK PAIN CAN BE CLASSIFIED IN ACUTE AND CHRONIC

Acute low back pain is the one that tends to self limit and resolve in thirty days. Typically follows by an event quite identifiable such as a trauma or an excessive physical exercise; each element of the column can be striked (disc, ligament, cartilage).

Particular reason for its occurred frequencies is from lumbago; therefore the cause of it is typically muscle that manifest a painful contracture and stabbing of the paravertebral muscles that stop the flexibility of the patient and causing him to lie down on his lateral side. In the real lumbago, the instrumental examination is negative.

A chronic lumbago can last for thirty days and it is sometimes lasts quite long; even in this case, it can be followed by an anatomy alteration of column or at a muscle contracture. In the last case, the pain loose its protection function, becomes aimless and disabling. Unfortunately, 10 – 15% of acute lumbago transform into chronic.

The specialist will ask the patient for how long the pain is occurred, if the onset has been acute or been insidious, if it is worsen by the cough or by the sneezing, if it is relieved by having rest and under what time of the day it usually present. It is important to know the profession of the patient (if the patient is a driver, if he remains by foot all the time or remains sitting for long time), eventual sport exercise and if the pain is attributable to a determined movement. It will evaluate as the patient walk, sits or undresses. Doctor will search where the pain is and its eventual irradiation to the inferior articular through specific test as Lasègue to emphasize a lumbar sciatica (Fig 6) or trial on foot to find out a neurology deficit, reflections parastisi in the specific area.

Amongst the most often examinations that are used nowadays, we would like to remind you to the Radiography in various part of the spine, the Resonance Magnetic Nuclear, Computerized Axial Tomography (CAT), bones' densitometry in suspected osteoporosis, bones scintigraphy in the metastasis and electromyography (EMG) to evaluate the neurologic impairment of limbs level.

MATERIALS AND METHOD USED IN THE NOWADAYS CENTER

SAMPLES

There were 129 patients recruited of the age between 18 and 60 years old in which 64 of them are women and 65 of them are men, with medium age of 39 years old, affected by Lumbago in Chronic phase caused by hernia disc. The exclusion criteria were the co-presence of other major diseases. From the first application with Diamagnetic Pump has been suspended other type of therapy whether by oral or by other type of Physical therapy.

TREATMENT

The treatment program has been articulated in x session, two or three times a week, 45 minutes in each session.

OBJECTIVITY

1. To improve the movement quality in the term of elasticity and fluidity.
2. To reduce and to manage the algic component.

FIG 5

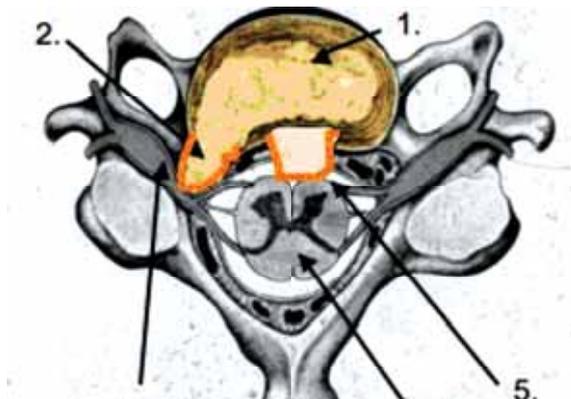
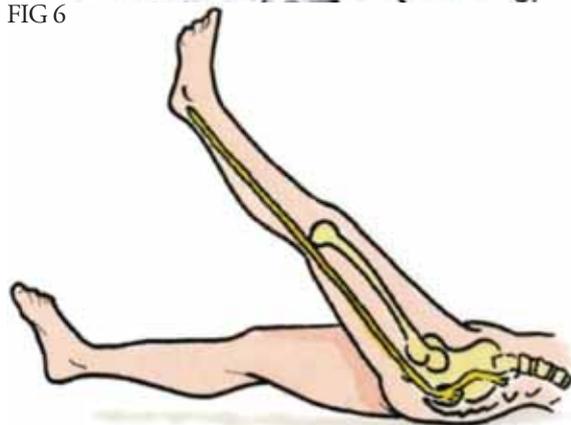


FIG 6



THERAPY WITH DIAMAGNETIC PUMP

CHRONIC LUMBAGO is a long inflammation and it consists of 3 factors:

1. **ACTIVE INFLAMMATION** caused by an **Acute inflammation** which become persist due to the **intervention factors** that alter the normal healing process.
2. **TISSUE DESTRUCTION**
3. **PERSISTENT ATTEMPTS OF THE TISSUE TO SELF REPAIR**

THIS SITUATIONS RESULTED TO A SYSTEMIC EFFECT



ALTERATION OF WATER EQUILIBRIUM

From **ELECTROLYTIC** point of view, the interested tissue which has **CHRONIC INFLAMMATION** present



INCREASE EXTRA CELL WATER
LOST OF INTRA CELL LIQUID



ALTERATION OF ELECTROLITE BRINGS A CONSEQUENT ALTERATION IN THE POTENTIAL MEMBRANE CELL





In the chronic inflammation, the edema increase since the osmosis pressure of the interstitial tissue is increased with the augmentation of extra cell liquid, increases the acidity of the extra cell accumulation and catabolite boost to protein and organic acid.



IT IS NECESSARY TO GENERATE THE CELL RE-POLARIZATION



TO REDUCE INFLAMMATION PROCESS INDUCING RE-EQUILIBRIUM OF LIQUID INTRA/EXTRA CELL



DIAMAGNETIC PUMP IN CHRONIC LUMBAGO

FUNCTIONS

Phase I

LIQUID MOVEMENT > INTRA – EXTRA CELL + CAPACITIVE DIATHERMY

By diamagnetic repulsion effect, the liquid in the extra cell compartments is removed from the area under treatment.

It facilitates the re-absorption of edema, post-traumatic cure, the waste elimination and stimulates the lymphatic circulation and the phenomenon related to it.

Further to its contribution of drainage process, the vasodilatation produced by the diathermy combined with diamagnetic in the Diamagnetic Pump device.

The magnetic field reacts on the intra cell liquid, confined at the internal part of the cell membrane, thanks to the Stationary wave produced by Magnetic Field under the form of Kinetic Energy, that act as catalyist in all energy activity, cell metabolism, ionic exchange, respiration, ATP production, catabolic elimination.

In Diamagnetic Pump, it presents as well an energy transfer regulator for the diathermy able to do different actions:

Micro Circulation action

Action on the adipocytes

Action on the gel mucopolisaccaridico

Action on the Interstitial layer

The diathermy applied at the same time of Magnetic field emission stimulates an hyperemia that allow to overcome the deficit of arterio-arteriolar and to increase the speed of velocity in the capillaries. In this way, it resolves micro circulatory stasis and regresses the edematous flow of interstitium.

The recovery of micro circulation raises the temperature gradient and enzymatic, reactivate the lipolysis. Further on, the friction caused by the current of product movement from the ionic charge produce a local augmentation and homogenous temperature that restore the normality of turn over adipocyte.

The diathermy restore the correct fluidity to gel form, intervene on the substance that constitute it, restoring the membrane selectivity that regulate the osmosis. This activity is magnified by the magnetic field effect and all factors that take into consideration of improvement, gel phase – solid phase, matrix.

The Diathermy increase the temperature, inducing an augmentation of macrophage proteolytic activity, reducing therefore the compactness of the connective fibers with consequence to reduction of echogenicity.

In normal operative conditions, the liquid movement induced in the diathermy process undergone a setback.

Indeed, following to the blood flow, the liquid accumulation that before occurred becomes more predominant, tends to increase due to the pressure equilibrium that restore the cell and for physical limit of mechanical confinement of external compartments.

Phase II

ENDOGENOUS STIMULATION > TARGET CELL + CAPACITIVE DIATHERMY

Each variable Magnetic Field that goes through a conductor induce in a contextual way as well as electrical current.

The human's body is a conductor of the II Species in which the magnetic field produced by DIAMAGNETIC CTU MEGA 18 system produce in electrical Field.

The various speed of magnetic field and high intensity that contradict this field generate therefore a cell bio stimulation.

The variation speed of magnetic field in CTU Mega 18 is very high (in the order of 1 ms) and the field's intensity of about 2 Tesla.

This technical and technology characteristic allow to excite and reconstruct the nerve fibers and muscle even at a very deep layer.

The diamagnetic stimulation is of endogenous type (developed directly at the internal part of tissue and not from external towards internal part as other normal electric stimulation).

Diamagnetic stimulation is of the isotrope type (homogenous for all tissue covered by magnetic field).

SUMMARY

PRIMARY EFFECTS OBTAINED BY BIOSTIMULATION OF DIAMAGNETIC PUMP ARE:

Increase periphery hepatic flow
The resolution of the muscle spasm
Acceleration of nerve stimulation and transmission
Anti edema and anti inflammatory action
Anti pain and anti inflammatory effect

Normalization of electric conductivity
Analgesic effect
Improving bone formation (osteogenesis)
Osteoblast membrane action and action on the bone's piezoelectric
Stimulation and normalization of production and removal process of collagen with better order and structure adjustment
Vascular stimulation
Increasing the mineralization and reactivate the dying cell
Increasing the bone's resistance
Increasing the electric activity on the fracture area
Edema solving
Bacteriostatic action
Acceleration of healing process on the soft tissue

Phase III

PAIN CONTROL

This program is specified for the analgesic therapy. They use the frequency below 300 KHz, for example 200 – 250 KHz which act and stimulate the nerve endings boosting and making the analgesic effect treatment immediately.

Phase IV

MOLECULAR IMPLANT

The penetrated drug are all active principle with diamagnetic property.

In case you do not know these drug characteristics, you can use water (or gel) as a vector to transporting the molecular in the tissue layer.

The parameter is carried out based on the implant depth, molecular dimension and the implant velocity. If the drug is cream or gel, you can apply directly on the tissue on the treated area.

If the drug is liquid, the procedure is to soak the gauze or cotton wool discs in it. Then you put the gauze or cotton wool discs on the treated tissue afterwards positioned the handle on top of the gauze or cotton wool discs.

It is possible to carry out the stratification of drugs with selecting the drug type and the depth of penetration into the tissue.

THE TREATMENT PROCEDURE WITH DIAMAGNETIC PUMP

TREATMENT	PROCEDURE	TIME
1	Liquid movement Intra 40% Extra 80% Diathermy – Capacitive Low Power in acute phase High Power in sub-acute phase	10 minutes
	Stimulation Endogenous Cellular Power 3 – 4	10 minutes
	Pain Control If there is pain	5 minutes
2	Liquid Movement Intra 40% Extra 80%	10 minutes
3	Stimulation Endogenous Stimulation Power 3 – 4 Diathermy – Capacitive	15 minutes
	Pain Control If there is pain Implant Molecular	5 minutes
4-10	Repetitive parameters, using the prog. No.3	

IMOLECULAR IMPLANT OF DICLOFENAC mg PARAMETER WITH DIAMAGNETIC PUMP

DEPTH	PA	HERTZ
According to diagnosis		
From 10mm to 30mm	400	5

ASSESSMENT METHODS

ASSESSMENT CRITERIA OF THE PAIN COMPONENT

The clinical assessment of pain has been measured by

I Subjective Parameters according to the VAS SCALE (Visual Analogic Scale from 1 to 10)

II Objective Parameters comes out from the pain responds from the Lasegue Manouvre, Wasserman, Valleix Points, assessment from sensitivity on the nerves area that involved in the treatment pathology, reflexes, osteo tendons,

The gathering of related information to the pain perception has been carried out before the initial of therapy, each 3 months data's revelations and 6 months revelations.

COMPLEX DEFINITION

It has been taken into consideration

OPTIMUM the pain symptom is gone
VERY GOOD improvement of about 80%
GOOD improvement of about 50%
WITHOUT SUCCESS lack of improvement or early suspension of treatment due to the unsatisfactory patient.

THE RESULTS

Revelation at the end of Treatment Program > T1

Group of 129 patients	Results	Value	%
	Optimum	41	31.78%
	Very Good	59	45.73%
	Good	21	61.27%
	Without Success	8	6.20%

FOLLOW UP After 3 months from the termination of Treatment Program > T2

Group of 129 patients	Results	Value	%
	Optimum	45	34.88%
	Very Good	69	53.48%
	Good	7	5.42%
	Without Success	8	6.20%

FOLLOW UP After 6 months from the termination of Treatment Program > T3

Group of 129 patients	Results	Value	%
	Optimum	47	36.43%
	Very Good	69	53.48%
	Good	5	5.42%
	Without Success		6.20%

FOLLOW UP After 9 months from the termination of Treatment Program > T4

Group of 129 patients	Results	Value	%
	Optimum	45	34.88%
	Very Good	69	53.48%
	Good	7	3.87%
	Without Success	8	6.20%

CONCLUSIONS

All patients involved in this treatment have completed Treatment Program according to the described Procedure. As you can see from the aforementioned Table, the improvement is quite significant, it even shows the improvement at T2 (after 3 months from the treatment accomplishment) and even at T3 (after 6 months from the treatment accomplishment).

From the application point of view, involved treatments with DIAMAGNETIC PUMP have underlined that this technology is not invasive, the tolerance of the patients towards the treatments are quite high.

Further on, there are no collateral effects occur during the treatment. On contrary, the Treatment has been carried out in a very short time, maximizing the obtained results with the Technology.

DIAMAGNETIC PUMP is a remarkable friendly user for the Therapist even after a short period of specific training. As a conclusion, the conservative approach to CHRONIC LUMBAR applied at 129 patients involved in the treatment Program with DIAMAGNETIC PUMP CTU MEGA 18 showed of being effective not only in reducing considerable the pain but increasing the treatment trim in the Treatment Program, still obtaining the results and maintaining the stability on medium period verified T4 at 9 months from the Treatment Program.

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