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## SUMMARY

Physiological Regulating Medicine (PRM) Homeomesotherapy in Acupuncture points is playing an increasingly more decisive and valued role in acute, subacute, and chronic arthro-myofascial pain therapy. This is due to recent findings regarding the mechanisms of action of low dose Homeopathy and of Acupuncture, and it represents an innovation, evolution, and optimization of conventional and unconventional mesotherapeutic techniques. The injection of PRM medicines for pain therapy in Acupuncture points presents a very low incidence of adverse effects (all of them negligible), and offers a therapy option which is safe, effective, and personalized according to symptomatological modalities due to the specific and unique characteristics of each of the injectable PRM medicines for pain therapy that can be combined in various ways.

- This publication offers a comparison between the results of the treatment of 196 patients affected by chronic musculotensive cervicodynia and divided into two homogeneous Groups treated with PRM Homeomesotherapy (Guna®-Neck + Guna®-Muscle + Guna®-Neural) vs. those treated with allopathic Mesotherapy (Ketoprofen). The results of this cohort, controlled clinical study underline the superior therapeutic benefits of PRM Homeomesotherapy, indicated as the method of first choice thanks to its nearly comparable quantitative effects but its superior qualitative effects (35.8% vs. 24.1% of very good results) without any adverse effects.

**KEY WORDS** MUSCULOTENSIVE CERVICODYNIA, TRIGGER POINT, MESOTHERAPY, HOMEOMESOTHERAPY, GUNA®-NECK, GUNA®-MUSCLE, GUNA®-NEURAL, KETOPROFEN, PHYSIOLOGICAL REGULATING MEDICINE

# PAIN MANAGEMENT IN CERVICAL CHRONIC MYOFASCIAL TRIGGER POINTS: PRM HOMEOMESOTHERAPY VS. CONVENTIONAL MESOTHERAPY

## - RESULTS OF A COHORT, CONTROLLED CLINICAL TRIAL

### INTRODUCTION

Musculotensive cervicodynia is a pathology with an enormous social impact (Yelin *et al.*, 1986). It provokes the loss of a considerable number of working days in various professional fields including those which require a physical effort with exposure to atmospheric elements (Hollander and Yeostros, 1963) and weight lifting (Walker-Bohe and Cooper, 2005), or, with increasing frequency, those which require a sedentary activity such as operators who spend long periods in a sitting position in front of a computer (Treaster *et al.*, 2006) or as car drivers; a low aptitude for sport-related activity and emotional tension (stress, anxiety, or depression) can aggravate the symptomatology (Borsalino, 2008) which is characterized by acute or chronic cervical pain and by neurovegetative phenomena such as headache, dizziness, vomiting, etc. due to the reflex contraction of short and long paravertebral muscles of the cervical spine, the trapezius, and the elevator of scapula as well as to irritation of the cervical sympathetic. With the great mobility of the cervical spine and thanks to the adoption of the upright posture (see p.

19), humans has always suffered from myofascial cervical pain to some degree at some point in his/her life (Escobar and Ballestros, 1987). - Perhaps ... the only exception is represented by the "giraffe women" of the Padaung Tribe - Myanmar and North Thailand (FIG. 1).

The conventional therapy is mostly based on the local or systemic use of NSAIDs and on physical and rehabilitative therapy, particularly massophysio-kinesitherapy and vertebral manipulations. The protracted use of NSAIDs is potentially dangerous: they are in first place among commonly prescribed drugs with serious adverse reactions (Coste *et al.*, 1995).

The conventional mesotherapeutic treatment mainly consists of subcutaneous injections (into the mesoderm, hence the term "mesotherapy") of steroids, NSAIDs and local anesthetics, administered both alone or in various combinations.

The therapeutic effect is obtained by:

- the direct decontraction mechanism on myofascial trigger points (interruption of the *loop* pain-spasm-pain);

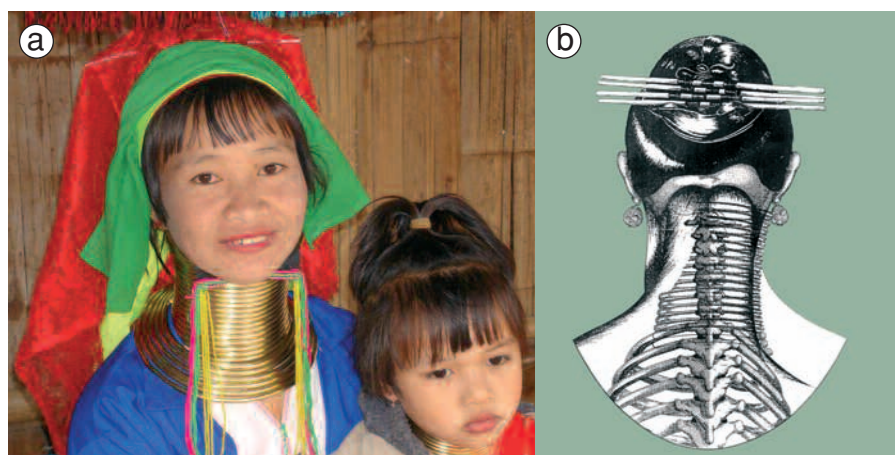


FIG. 1

① “Giraffe woman” of the Padaung Tribe. Even from an extremely early age, a progressive number of up to 25 brass rings are placed around the neck of women for esthetic reasons. The total structure can weigh over 5 Kg. The giraffe women show an extremely thin and long neck, and only very limited movements are allowed. Nai-Soi, Long Neck Village. Chiang Mai Prov. –Thailand. Photo: E. Guarie, 2008.

② Schematic drawing of cervical vertebrae and positioning of the rings in a Long Neck Woman.

- reflex modulation by neuromodulators which are present on various levels of the nociceptive stimulus from one or a few contiguous metamers.

- PRM Homeomesotherapy develops its therapeutic action through the stimulation of the Acupuncture points [variability of their surface (from some mm to some cm ø), often coinciding with the trigger points (TPs)] with a neuroreflex mechanism which integrates the aforementioned two tied to the stimulation of the A delta fibres and of the free nerve endings of unmyelinated fibers of small size (type c) (Milani, 2006) which, at the level of the posterior horn of the spinal cord, close the “gate”, with impulse blockage (Melzack, 1981).

The Acupuncture points have a characteristic metameric innervation that make them particular and privileged therapeutic *loci*. In this aspect, from a chronological view, MacKenzie’s pain points (1920), Head’s Zones - referred areas (1926), Lewis’ referred pain areas (1942), Sola’s trigger points (1955), Jarricot’s anterior and posterior thoracic-abdominal reflex dermalgia (1932; 1971; 1980), hypersensitive musculo-cutaneous areas (Bourdiol, 1972; 1981; 1985), muscular trigger points of Travell and Simons (1983) and Travell and Daltz (1986), reflex therapy Acupuncture points (Milani, 1978; 1980a, 1980b; 1983), and at

least 70% of Weihe’s points (Milani, 2004), 80% coincidental among these, are all important and irreplaceable tools for **diagnosis** (viscero-cutaneous, viscero-muscular, muscular-cutaneous reflexes), and, above all, for **therapy** (cutaneous-visceral, cutaneous-muscular, and musculo-muscular reflexes).

## PATIENTS AND METHODS

The objective of this cohort (2 orthopedic Clinics and 1 rheumatology Clinic in the Republic of San Marino) and controlled clinical trial is the comparison of the efficacy of conventional Mesotherapy vs. PRM Homeomesotherapy in the treatment of **chronic musculotensive cervicodynia**.

The diagnosis of musculotensive cervicodynia is essentially clinical, and based on the presence of TPs.

Until 1995, most quality homeopathic clinical publications concerned studies placebo-controlled (92%) while from 1996 to 2007 (Milani, 2008), most publications regarded control vs. corresponding allopathic treatment (58%). The World Medical Association (WMA) published in 2003 an explanatory Note for paragraph 29 of the Helsinki Declaration (1<sup>st</sup> edition: October 2001; 2<sup>nd</sup> edition: March 2003) on clinical trials in humans.

The explanatory Note states that “*must be paid very close attention to the comparisons made in clinical studies vs. placebo*” and that “*these studies should only be carried out when no other options are available and, however, for less serious pathologies that do not provide serious risk for patient’s health*”.

Furthermore, in countries of the European Union, the physician must obtain a **written informed consent** from the patient before the therapy.

In this way, no patient would volunteer himself/herself for a placebo therapy as he/she will not receive any real benefit and will be wasting precious time necessary for the resolution of his/her health problems. Moreover, placebo treatments are unethical and not *patient-oriented* (Milani, 2006) as current trends in medicine suggest.

- This study enrolled **196 patients** [81 M (41.3%); 115 F (58.7%)] between 22 and 53 years of age, and was carried out between January 2007 and June 2008. These individuals complain the appearance of the symptoms somewhere between 6 and 12 months prior to their enrollment. 79% of the enrolled patients undertake jobs which obligated them to spend many hours behind a desk and/or driving or doing heavy jobs. None of them had undergone physiokinesitherapy or manipulative therapies.

- This study excluded all patients with radiographic evidence of grave arthrosic arthropathy (Haas Scale III, IV) or with symptoms of radicular compression (cervicobrachialgia) as well as patients suffering from facet joint syndrome (Martelletti and van Suyilekom, 2004) or from fibromyalgia in accordance with the definition of the American College of Rheumatology (ACR) (1996) or with a medical history of allergies to drugs or gastrointestinal, hepatic, renal pathologies, or cancer.

The patients included were divided into **two Groups** which were initially planned for randomization: however, once the patients were informed (written informed consent) of the possible adverse effects related to conventional pharmacological Mesotherapy and to



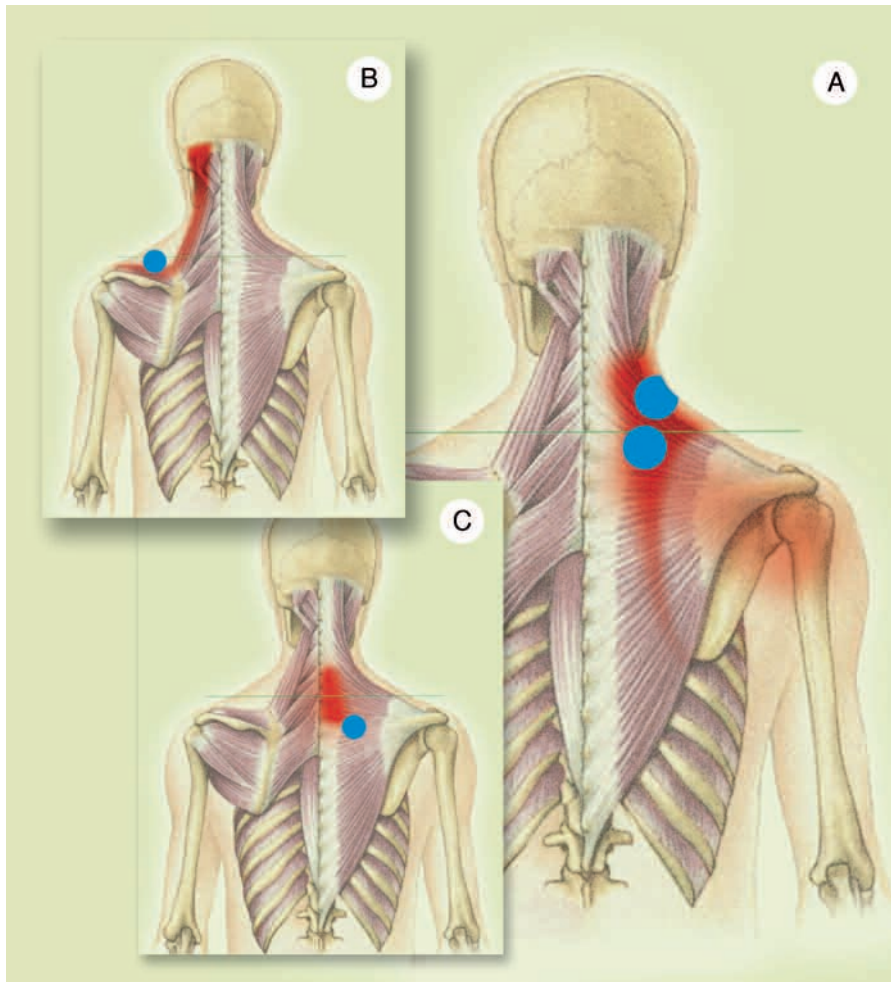


FIG. 2

**Localization of Trigger Points (blue) and the respective zones of referred pain (red) of the superior trapezius (A), inferior trapezius (B), and the elevator of scapula (C).**

the recent guidelines from the International Society of Mesotherapy (S.I.E., Brussels – Belgium) (2005).

#### ► Group B = Physiological Regulating Medicine - PRM

**109 patients** (55.6% of the total number of patients included in the study; 50 M, 59 F) between 22 and 52 years of age, treated on the GB20 bilateral, BL10 bilateral, GB21 bilateral, TH15 bilateral, SI15 bilateral and BL11 bilateral Acupuncture points (total points treated = 12) (FIG. 3) with the injectable ampoules registered in the USA: **Guna®-Neck**, 2 vials + **Guna®-Muscle**, 2 vials + **Guna®-Neural**, 2 vials.

One ml of this cocktail was injected subcutaneously into each Acupuncture point with a 4mm 27G needle.

The small amount of combined drugs injected into every single Acupoint was possible due to the capacity of PRM medicines to transmit their information in a *low dose, low titred*, and electromagnetic manner (rules of coherence according to Del Giudice and Vitiello, 2006).

- *Low dose* active ingredients (nanopharmacology) can be studied in accordance with Toxicology and Pharmacology (Milani, 2008), and provide a specific rationale based on the suggestions of the standard

the harmless characteristics of PRM Homeomesotherapy, most of them (109 vs. 87) choose the latter therapeutic option.

#### ► Group A = allopathic

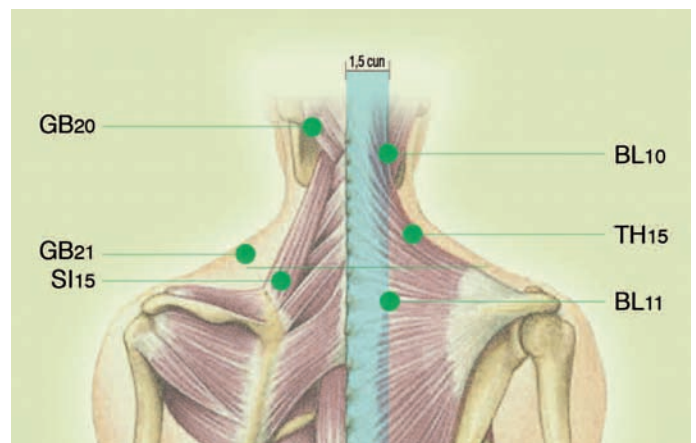
**87 patients** (44.4% of the total number of patients included in the study; 31 M and 56 F) between 25 and 53 years of age, were treated with Mesotherapy in the points of pain and in the TPs\* of the cervical muscles (FIG. 2) with *ketoprofen* (KPF) (2-[benzoyl-phenyl]-propionic acid), two 2 ml vials (100 mg each) with a 4 mm 27G needle. KPF is a commonly used drug for pain relief, inflammation, and joint swelling associated with different forms of arthritis and other algic pathologies in the soft tissues. It belongs to the NSAID class of pharmaceuticals. Known side effects of KPF include: nausea, gastric and/or abdominal pain and diarrhea. KPF was chosen as it is the only NSAID that has **officially recognized indications for mesotherapeutic administra-**

**tion.** Furthermore, Airaksinen *et al.* (1993) demonstrated the efficacy of KPF vs. placebo in the treatment of soft tissue pain of traumatic origin; so this drug was already the subject of careful experimentation vs. placebo.

- Our experimentation vs. KPF, therefore, bypasses the testing vs. placebo.

The cocktail with other drugs has been excluded in accordance with

**FIG. 3**  
**Local Acupuncture Points.** All of the points were bilaterally injected with a 1 ml drugs combination of Guna®-Neck + Guna®-Muscle + Guna®-Neural per point. 1.5 *cun* = 2 cm on average.



\* Positive TP is painful when the applied thumb pressure (4 kg/cm<sup>2</sup>) is sufficient to blanch the nail bed of the practitioner's (Milani, 2006).

Homeopathic Materia Medica and the recent discoveries in such fields as Physiology and Physiopathology. These concepts make it possible to analyze the effect of each active substance contained in the 3 PRM injectable formulations utilized in this study:

#### GUNA®-NECK

For a better, more effective understanding of the therapeutic effect of Guna®-Neck ampoules, we can select **4 different pharmacological action cores** as follows:

##### 1 Homeopathic antalgic core

*Magnesia phosporica* 8X; *Picricum ac.* 10X; *Nux vomica* 10X; *Crotalus horridus* 10X.

##### 2 PNEI antalgic core

*Beta-Endorphin* 4C (Milani, 2007).

##### 3 Anti-inflammatory core

*Anti Interleukin 1α* 4C; *Anti Interleukin 1β* 4C (Arend, 1991; Milani; 2007, 2008).

##### 4 Antidegenerative core

*Cartilago* 4X; *Intervertebral disk* 4X; *Silicea* 4X.

#### GUNA®-MUSCLE

**5 different pharmacological action cores** as follows:

##### 1 Muscular rheumatism core

*Colchicum autumnale* 6X; *Lithium benzoicum* 8X.

##### 2 Sprain pain core

*Hypericum perforatum* 4X.

##### 3 Spastic pain

*Colocynthis* 4X;  
*Cuprum sulphuricum* 4X.

##### 4 Contusive muscular pain

*Arnica montana* 4X; *Belladonna* 6X.

##### 5 Anti-degenerative core

*Muscle tissue* 4C; *Procain chloride* 2X; *Interferon γ* 4C.

#### GUNA®-NEURAL

**3 different pharmacological action cores** as follows:

##### 1 PNEI antalgic core

*Beta-Endorphin* 4C, as in Guna®-Neck.

##### 2 Anti-inflammatory core (inflammatory aetiology neuropathies and rheumatic aetiology)

*Kalmia latifolia* 2X; *Ferrum phosphoricum* 2X; *Colocynthis* 4X; *Paris quadrifolia* 6X; *Gnaphalium polyccephalum* 6X; *Iris versicolor* 8X; *Aconitum napellus* 8X; *Formica rufa* 8X.

##### 4 Anti-degenerative core

*Neurotrophin* 4 4C.

- Highly significant comparability (homogeneity) between the 2 test Groups **before** treatment (TAB.1):

1) Average age (not shown in TAB.1):

- Group A = 44.6 years

- Group B = 45.2 years

2) Pain

- Group A = 13.4

- Group B = 13.8

3) Dizziness

- Group A = 2.0

- Group B = 2.2

4) Articularity in degrees (neck movement)

- Group A = 248.6°

- Group B = 250.7°

5) Trigger points

- Group A = 3.2

- Group B = 3.7

Since both Groups are **homogeneous** (number, sex, age, symptomatology), the results of therapy are **comparable**.

The clinical trial - therefore - complies with homogeneity criteria for the compared Groups.

- **6-8 sessions** once a week of allopathic Mesotherapy or PRM Homeomesotherapy were carried out with single-needle 4 mm 27 G to all of the 196 individuals included in the study (total therapeutic time: 40-55 days). Furthermore, an home therapy of deep drainage with **Guna®-Matrix** drops, 10 drops x 5 consecutive days per week x 2 months (the entire duration of the Mesotherapy or PRM Homeomesotherapy treatment) was prescribed **for all** of the patients included in the study.

The final evaluation (follow up = 4-6 weeks after the last treatment) was carried out according to **subjective** and **objective** parameters as well as the incidence of adverse effects.

#### • SUBJECTIVE PARAMETERS

Two parameters were considered:

1) Cerviconuchal pain: at re-awakening and stress-induced.

For the evaluation of the pain symptomatology, the Scott and Huskisson (1976) Visual Analogic Scale (VAS) (score from 0 to 10) was used and the sum of the parameters at re-awakening and stress-induced were evaluated within a range of 0-20.

PARAMETER	GROUP A ALLOPATHIC MESOTHERAPY	GROUP B PRM HOMEOMESOTHERAPY
PAIN	13.4	13.8
DIZZINESS	2.0	2.2
NECK MOVEMENT	248.6°	250.7°
TRIGGER POINTS/ZONES	3.2	3.7

TAB.1

Average parameter values **before** treatment. These values show the comparability between Group A = allopathic Mesotherapy = KPF and Group B = PRM Homeomesotherapy = Guna®-Neck + Guna®-Muscle + Guna®-Neural.

The VAS (unidimensional subjective method) is more useful for the evaluation of chronic pain in comparison with the Verbal Rating Scale (VRS; Keele, 1948), the Numerical Rating Scale (NRS; Donnie, 1978), the Analogue Chromatic Continuous Scale (ACCS; Grossi, 1983).

Recently, Ottaviani (2008) proposed the Roland-Morris Low Back Pain and Disability Questionnaire modified for cervical pain. Nevertheless, the above mentioned Questionnaire it is not easily understandable for all people.

2) Dizziness was evaluated according to the following point values:

- 0: absent
- 1: subjective attack of dizziness provoked by rapid postural variations
- 2: subjective attack of dizziness provoked by even minimal and slowly executed postural variations
- 3: sense of instability in orthostatism.

#### • OBJECTIVE PARAMETERS

Two parameters were considered:

1) The myofascial TPs of the *superior* and *inferior trapezius* on the more painful side, index of the musculotensive component:

- 0: TP absent
- 1: TP present (solid nodule) but not painful
- 2: TP present and painful upon deep palpation
- 3: TP present and painful upon superficial palpation.

2) Total articular range, expressed in degrees (total: 300°) based on the parameters of normalcy according to Cipriano (2003):

- flexoextension: 90° (45° + 45°)
- rotations: 120° (60° + 60°)
- lateral inclinations: 90° (45° + 45°).

#### • ADVERSE EFFECTS

Classified according to the following values:

- 0: no adverse effects
- 1: temporary local skin reaction in one or more points of injection
- 2: temporary organ disorder which did not interfere with the therapy course
- 3: organ disorders which required treatment withdrawal.

### RESULTS

Results were collected with a **point system** (Zenker *et al.*, 2002) in which all examined aspects were considered: the subjective profile as well as objective aspects and adverse effects.

#### 1) SUBJECTIVE PARAMETERS

(maximum points =10):

1a) *Pain* = **reduction** in the Scott-Huskisson Visual Analogic Scale:

- of at least 0-3 degrees: 0 points
- of at least 4-7 degrees: 3 points
- of at least 8 degrees: 6 points.

1b) *Dizziness* = **reduction** with respect to the initial valuation:

- unchanged: 0 points
- of 1 level: 2 points
- of at least 2 levels: 4 points.

#### 2) OBJECTIVE PARAMETERS

(maximum points =10):

2a) *Articularity* = **total increase** in the three plans:

- 20°: 0 points
- between 20° and 50°: 3 points
- > 50°: 6 points.

2b) *Trigger Points*

- persistence of non-painful TP before the treatment: 0 points
- persistence of painful TP: 0 points

- persistence of non-painful TP: 3 points
- TP disappeared: 4 points.

The valuation of the trigger areas and TPs was deliberately differentiated, in as much as, as reported in the literature (Wachter and Prien, 1988), and we observed in this trial, it is difficult to always achieve their complete eradication.

#### 3) ADVERSE EFFECTS

- disturbance of organ which caused the treatment withdrawal (drop out) : 0 points
- transitory organ disorder which did not alter the continuation of the therapy: 2 points
- temporary local reaction in one or more points of injection: 4 points
- No adverse effects: 6 points.

The **comprehensive valuation** of the results was as follows:

**null: 0 - 7 points**

**low: 8 – 14 points**

**good: 15 – 21 points**

**very good: 22 – 26 points.**

After 4-6 weeks after the last treatment, 84 patients of Group A (3 dropped out in the course of the therapy) and the 109 patients of Group B (no drop-outs) were re-evaluated for the following parameters:

1) Pain

- Group A = 6.2
- Group B = 4.1

2) Dizziness

- Group A = 1.2
- Group B = 0.4

#### POINTS

- Group A = 6.1
- Group B = 7.1

3) Articularity in degrees

- Group A = 273.5°
- Group B = 285.5°

## 4) Trigger points

- Group A = 2.3
- Group B = 0.6

## POINTS

- Group A = 6.0
- Group B = 5.6

## 5) Adverse effects

- Group A = 14
- Group B = 6

## POINTS

- Group A = 5.5
- Group B = 5.9

## TOTAL POINTS

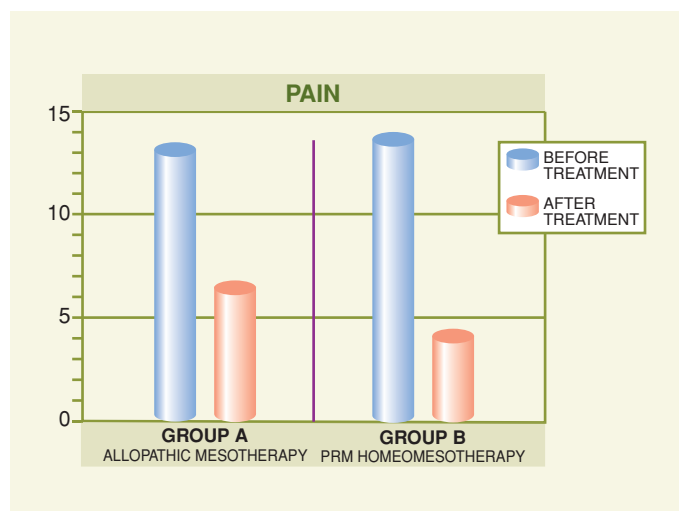
- Group A = 17.6
- Group B = 18.6

The differences between the 2 Groups **before** and **after** therapy are shown for the following parameters: PAIN (TAB.2), DIZZINESS (TAB.3), ARTICULARITY IN DEGREES (NECK MOVEMENTS) (TAB.4), TRIGGER POINTS (TAB.5), and ADVERSE EFFECTS (TAB.6).

- The comprehensive results of the therapy are shown in TABLES 7 and 8.

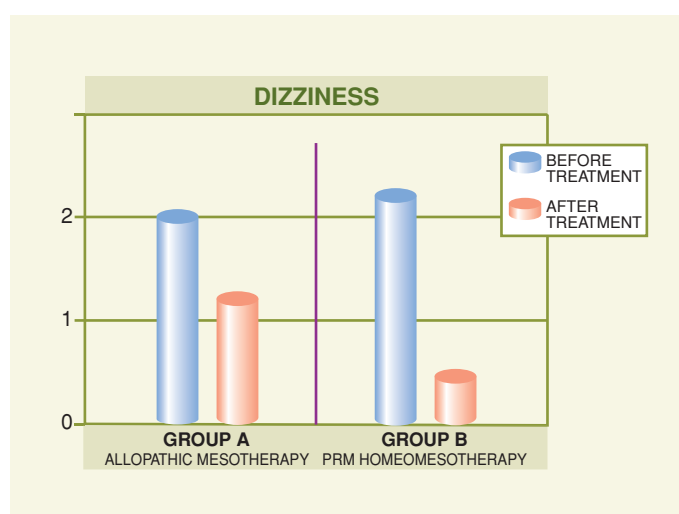
## DISCUSSION – CONCLUSIONS

The results of the therapy with conventional allopathic Mesotherapy vs. PRM Homeomesotherapy for pain management in cervical chronic myofascial TPs confirm the efficacy of the 2 antalgic therapies compared in 2 very homogeneous Groups of patients: in both Groups, a highly positive response with regard to pain and neurovegetative symptoms was obtained (allopathic Mesotherapy: 85.7%; PRM Homeomesotherapy: 85.4%). Major differences were founded in the tolerability of the treatment (TAB.6). In particular, the 4 transitory local reactions of PRM Homeomesotherapy Group were represented by small erythematous reaction corresponding to the points of injection, appearing immediately after the first session and resolving itself after 1 hour with the local application of **Tamanu Arnica™** cream. The observed transitory local reactions occurred differently in the allopathic



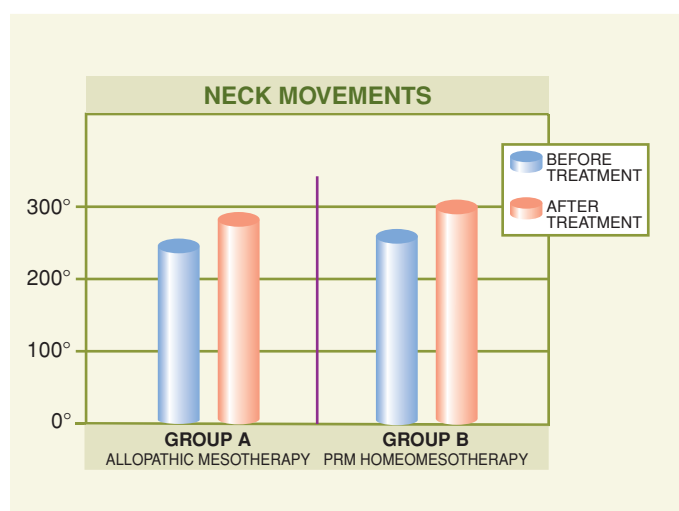
TAB.2

**Pain.**  
Comparison between the 2 Groups before and 4 weeks after the last treatment.



TAB.3

**Dizziness.**  
Comparison between the 2 Groups before and 4 weeks after the last treatment.



TAB.4

**Articularity (neck movements).**  
Comparison between the 2 Groups before and 4 weeks after the last treatment.

Mesotherapy Group: a greater number (12) was observed and, in particular, the reactions occurred in 9 out of 12 (75%) cases after the 1st or 2nd session. Once again, in terms of a local reaction, 7 patients of the allopathic Mesotherapy Group (8%) complained, after a variable period of 1-2 months

after the final session, a connective tissue reaction in 1 or more points of infiltration with KPF as solid nodules of a *rice grain size* or larger and painful upon deep palpation, even though not always spontaneous. None of these tissue reactions was reported by patients in the PRM



Homeomesotherapy Group.

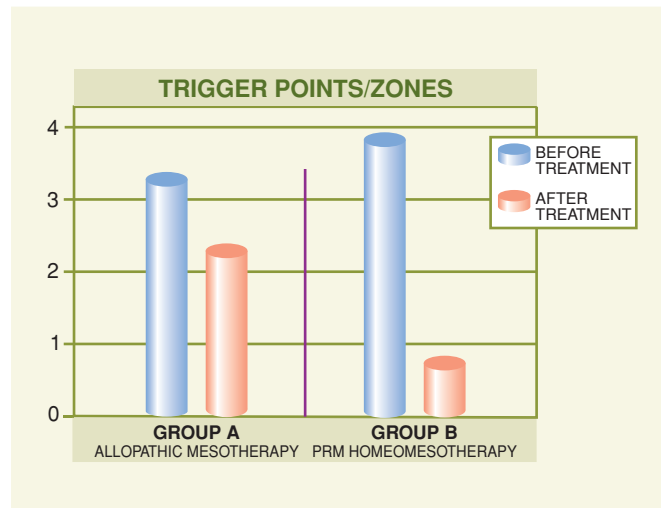
Eight patients of the allopathic Mesotherapy Group (9%) reported symptoms related to acute gastropathy within the first three sessions: 3 of these (1 was particularly serious) had to withdraw the treatment and were referred to a gastroenterologist for the related consequences.

- This cohort, controlled clinical study demonstrates that PRM Homeomesotherapy is an effective therapy in the treatment of symptomatology of pain and of neurovegetative phenomena of cervical origin, practically without local and/or systemic negative side effects and can be suitable as a method of first choice due to its comparable quantitative effects, but its superior qualitative effects (35.8% vs. 24.1% very good cases) to its allopathic treatment counterpart.

One recent study by Biffi (2008) suggests that the **oral, sublingual, or endonasal** administration of injectible biotherapeutic drugs triggers the Bystander Reaction (Heine, 2004) and these methods of administration can be effectively used in *needlephobic patients*, though the quantity and frequency of administration should be increased (in acute cases: 2 vials of each formulation per day x 10 consecutive days; in chronic cases: 1 vial per day x 20 consecutive days). ■

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**TAB. 5**

Trigger Points/Zones. Comparison between the 2 Groups before and 4 weeks after the last treatment.

LOCAL OR GENERAL REACTION	GROUP A ALLOPATHIC MESOTHERAPY number of patients	%	GROUP B PRM HOMEOMESOTHERAPY number of patients	%
NONE	67	77%	105	96.3%
LOCAL TEMPORARY REACTION IN ONE OR MORE INJECTION POINTS	12	13.8%	4	3.7%
TEMPORARY ORGANIC PATHOLOGY WITH CONTINUATION OF THE THERAPY	5	5.7%	0	0
ORGANIC PATHOLOGY WITH INTERRUPTION OF THE THERAPY (DROP OUT)	3	3.5%	0	0
TOTAL	87	100%	109	100%

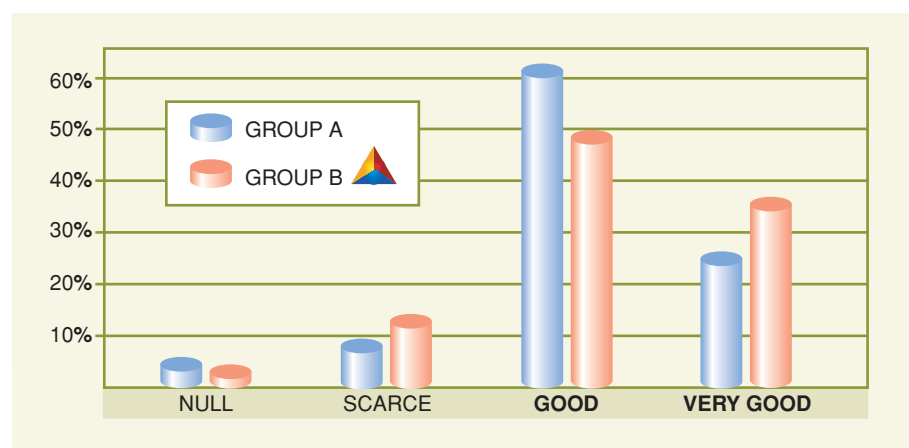
**TAB. 6**

Adverse effects in the 2 Groups.

RESULT	GROUP A ALLOPATHIC MESOTHERAPY number of patients	%	GROUP B PRM HOMEOMESOTHERAPY number of patients	%
NULL	4	4.8%	2	1.8%
SCARCE	8	9.5%	14	12.8%
GOOD	51	60.7%	54	49.6%
VERY GOOD	21	24.1%	39	35.8%
TOTAL	84*	100%	109	100%

\* 3 drop out patients in the included 87

**TAB. 7**



TAB. 8

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