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Evaluation of the clinical effectiveness of microkinesitherapy in post-traumatic cervicalgia. A randomized, double-blinded clinical trial.

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SUMMARY

Objective: To evaluate the effect of a microkinesitherapy session on pain and the amplitudes of flexion-extension in post-traumatic acute neck pain. *Methods*: Randomized double blind clinical trial involving two groups of patients. The microkinesitherapy group benefitted from the check-up treatment sequence, the control group from a check-up simulation sequence. The primary outcome measure was evolution of pain, secondary endpoint amplitudes of movement. *Results:* 29 patients were studied: 15 in the microkinesitherapy group and 14 in the control group. A significant decrease in the visual analog scale (0-10) of pain was noted for the microkinesitherapy group (5,2 ± 2,3 at initial check-up versus 2.5 ± 1.7 in the second check-up, p <0.001), but no decrease in the control group (4,0 ± 2,3 initial check-up versus 3,1 ± 2,4 in the second check-up, ns). The evolution of the amplitude of flexion-extension was significant for the microkinesitherapy group (95° ± 29° ° in the first check-up versus 107° ± 27° in the second check-up, p <0.02) but no improvement in the control group (104° ± 26° initial check-up versus 107° ± 28° in the second check-up, ns). *Conclusion:* Our study shows that an early microkinesitherapy session is effective on pain and recovery of flexion-extension in the treated group.

Keywords: Post-traumatic neck pain, microkinesitherapy, therapeutic trial, double blind, randomized study.

1. INTRODUCTION

The main causes of acute post-traumatic neck pain are road traffic accidents, sports injuries and falls. These events can lead to musculoskeletal and soft tissue injuries with development of functional disorders, such as pain, headache, vertigo and joint amplitude limitation [1]. According to the International Association for the Study of Pain, acute pain is pain that has been present for less than 3 months, while chronic pain is pain that has been present for more than 3 months [2]. For this study, we used the Bone Joint Decade Task Force's classification proposal as a reference standard - patients under study were part of grade 1 and 2 with category 2-pain duration [3]. A review of the literature recommends muscular exercises and early mobilization, which seem to be the best treatment option for the recovery of mobility. There is no evidence of any effectiveness on pain nor on mobility [4] for other techniques such as massage, application of heat, cervical mobilization only, transcutaneous electrical nerve stimulation, pulling, collars, electromagnetic therapy, correction techniques by positioning, spray and stretching treatment, neck school exercises [5,1,6], and ergonomic adaptations [7].

The American Physical Therapy Association (APTA) has issued clinical guidelines for manual therapy emanating from literature review and expert opinions [8]. These guidelines are in contradiction with other existing guidelines that specify that manual therapy provides no significant benefit [5, 9]. None of these studies examined microkinesitherapy. The aim of microkinesitherapy is, among other things, to cure post-traumatic pain by easing muscle tension induced by trauma. The first step consists in searching the muscle and joint elements that have been damaged by trauma with a specific "micropalpation" check-up. This micropalpation consists in a two handed sliding technique of palpation. In a second step, the physiotherapist normalizes the tension of the damaged muscles by very gently stretching the muscles corresponding to the dermal area detected by the "micropalpation" chech-up. The first step is based on an accurate mapping, empirically elaborated from embryological data. In the embryonic stage, embryologists describe the division of the paraxial mesoderm into three portions: sclero, myo, dermatomes [10]. At each metameric segment, interactions exist between the bones,

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muscles and dermal areas. In microkinesitherapy practice, using palpatory research, the developers of the technique have established empirically correlations between muscular areas and dermal areas. The micropalpation of the latters enables to determine if a dermal area shows a restriction of mobility. Based on this finding and the mapping established by the developers of the technique, the corresponding muscle can be deduced. For example, a restriction of mobility of the dermal area of the lower 2/3 of the inner thigh corresponds to a dysfunction of the diaphragm [11]. Yet, it has been demonstrated that such a dysfunction -which can be of traumatic origin- can cause pain at the C3-C4, C4-C5 and C5-C6 vertebral levels [12]. Indeed, the diaphragm was formed at this metameric level during the end of the first month of gestation [13].

To our knowledge, no double-blind assessment has been made on the effectiveness of microkinesitherapy as regards this pathology [14], which justifies the objective of the study, namely: to evaluate the effectiveness of microkinesitherapy treatment in first-line cervical trauma of less than three months duration. Assessment was made according to the evolution of two parameters of pain and joint mobility, before and after treatment. This was compared with treatment simulation. The hypothesis is that the effect of treatment will be significantly different from the effect of simulation.

2. PATIENT AND METHODS

2.1. Patients

Inclusion criteria

The patients included in the study met the following inclusion criteria: consenting, between 18 and 60 years old, without distinction of sex, with less than 3 month post-traumatic neck pain corresponding to category 2 according to axis 4 (duration) of the Bone Joint Decade Task Force's classification [3], benefitting from social security cover, with an eight day drug treatment prescribed by their physician and containing non-steroid anti-inflammatory drugs, analgesics and muscle relaxant drugs, according to the following treatment protocol: Diclofenac 50mg: 3 pills / day; Paracetamol: 3 pills / day; and Thiocolchicoside: 3 pills / day.

Some publications [3] having highlighted the existence of favorable spontaneous evolution of neck pain in the first week; so we decided to add an inclusion criterion: that the time between the trauma and the first check-up should be more than seven days.

Exclusion criteria.

The exclusion criteria were the following: patients who could not be followed under the protocol; patients who could not take the recommended drug treatment or took another treatment than the one provided for by the protocol; patients treated for prior neck pain, patients already treated by physiotherapy and microkinesitherapy for this pathology; patients with non-traumatic neck pain, whether of inflammatory, infectious, or neurological origin; patients previously treated with microkinesitherapy for another pathology; patients with neck pain associated with cervicobrachial neuralgia.

2.2 Protocol

The experimentation was conducted under a research protocol with direct benefit. This protocol was accepted by the advisory committee in biomedical research of Grenoble 2 on July 10, 1998 whose president was L.Barret (Ref: 98 / ACDM / 1 / C2). Explorations were conducted in accordance with good clinical practice.

Recruitment procedure

The patients were referred by 18 physicians from the Grenoble region informed of the study to 5 physiotherapists trained in microkinesitherapy (ten years of practice at least) and participating in the study. Each recruiting physician participating in the study had been equipped with a set of documents providing information on the study aims, the protocol and the inclusion and exclusion criteria. The physicians made the diagnosis, prescribed medication to the patients in accordance with the protocol and, in addition, proposed participation in the study. With this strategy, patients did not risk under treatment. Diagnosis and drug treatment were neither to be discussed nor modified by investigating physicians during the protocol.

The patients willing to participate in the study were acquired verbally by the physician and the volunteer received an information leaflet describing the study aims, a presentation of the research group and a description of their own expected participation. Then, the patients contacted the coordinator themselves within less than 3 days after the consultation if they volunteered. The latter gave them a first appointment for inclusion. During their inclusion into the study, patients were randomly divided into two groups: a microkinesitherapy group and a control group. The team involved in the study consisted in eighteen recruiting physicians, the coordinator, two investigating physicians and five physiotherapists.

Structures and place of data collection

The study was carried out in a physiotherapy practice with an exam room reserved for the investigating physician and a treatment room for the physiotherapist intervening with the patients included in the study. Both investigating physicians were the only ones to have the key of a closed metal locker. The five physiotherapists had another metal locker to which they were the only ones with access.

Interventions for each group

The patients were monitored during two consultations in a 10-day interval. During the first consultation (C1), the investigating physician verified the patient's conditions of inclusion. During inclusion, the protocol was explained once more to the patient and the latter signed the consent form. He then received a number corresponding to his entry number in the experiment to grant anonymity.

A first check-up was performed by the investigating physician one-to-one with the patient. Patient support was then performed by the physiotherapist. During the second consultation (C2) the check-up was performed in the same conditions as in C1 and by the same investigating physician. If new symptoms, whether related to the pathology or drug treatment occurred, the patient was invited to consult his attending physician again. In this context, the study was unblinded in order to facilitate medical support.

Conduct of the support session by the physiotherapist

For the patients who received the microkinesitherapy treatment (group 1), the physiotherapist searched the muscle and joint elements that had been damaged during trauma, by a specific micropalpation check-up. He then attempted to normalize the muscle tension by very gently stretching the muscle corresponding to the dermal area detected by a specific micropalpation check-up [11].

For the patients in the control group (group 2), the physiotherapist performed a treatment simulation on muscular and dermic areas with no embryological link with the cervical region. These actions were indistinguishable for the investigating physician untrained in microkinesitherapy techniques, as well as the patient, thus guaranteeing respect of the double-blind procedure.

Stopping rules

The difficulties of recruiting patients, the availability of the investigating physicians and the complexity of the organization of such a research in a liberal sector prompted us to limit the period of patient inclusion to a period of 3 years at the end of which 29 patients were included. We started with the first patient on May 6th 1999 and ended with the last patient on May 16th 2002. The investigating physician in charge of the data analysis had a professional reorientation along the way. This research was therefore postponed until some university professors joined the team in 2015 to finalize the analysis in compliance with CONSORT's new norms and write the manuscript.

2.3. Evaluation criteria.

Choice of the assessment criteria

The choice of the assessment of pain as the main criterion is motivated by the will to test the effectiveness of microkinesitherapy on this parameter. The choice of the assessment of the amplitudes of flexion-extension as a secondary criterion is justified by the frequency of trauma having an impact on this movement. During the first (C1) and the second consultation (C2) the evaluating physician noted the following elements provided by the patients on numbered and anonymized files according to the randomization procedure. The patients assessed their spontaneous pain at rest using a visual analog scale ranging from 0 to 10 according to the protocol based on the use of a scale [15]. The patients also assessed some symptoms associated with neck pain using a scale ranging from 0 to 10. The symptoms taken into account concerned perception (vertigo, tinnitus), cognition (quality of sleep and concentration) and emotion (anxiety and mood). Then, the patients actively made flexion-extension movements, left-right rotations and left-right lateral inclinations. Amplitudes were assessed using the three axes-goniometric headset Cervicontrol ® (Promokiné, Amiens, France).

Choice of the statistical method and the size of the sample

To detect a possible modification of the values of the two variables studied between the two check-ups, the Student "t" test (comparison of averages of matched data) was chosen. Sixty patients were planned to be included in the protocol. This number allows satisfying the conditions of validity for the reasonable use of the chosen statistical tool. The analysis was carried out on an intention to treat basis.

2.4 Randomization

Method for the random distribution sequence

Experimentation was organized to respect the random allocation of patients in the two treatment groups and the double-blind procedure.

Type of Randomization

Random allocation was made from a list drawn up by a sampling method by blocks of 6. Each inclusion serial number corresponded to an envelope containing the treatment code to be applied to the patient.

Mechanism for the randomized allocation sequence

The envelopes, according to the determined size of the sample for this study were prepared by a person who was not connected to the team of practitioners involved in the study. The envelopes were opaque and sealed. Each type of treatment was written on half an A4 sheet easily identifiable by 4 round letters (0000) or 4 bar letters (XXXX). The code had been created so that the patient could not understand it when the physiotherapist opened the envelope. Each envelope contained one and only one letter code. In order to ensure a homogeneous distribution of the interventions of physiotherapists, the envelopes were distributed by series of 6.

Each series had three envelopes containing a 0000 code and three envelopes containing a XXXX code. When a series of 6 envelopes were constituted, they were mixed together. A number was written on each envelope in chronological order. On the following series, the chronological order resumed from the last figure of the previous series. Thus, all the envelopes were numbered from 1 to 60 and were classified into a container provided for this purpose by series of 6. The investigator, at the end of the first check-up and just before the intervention of the physiotherapist, took the first envelope of the series being distributed. He gave the patient the envelope.

The patient went into the physiotherapy room to receive the treatment. The patient was requested not to give his name to the physiotherapist. The latter could not exchange any word with the patient apart those required for his installation. The investigator did not know the code in the envelope nor its meaning. This procedure aimed at keeping the patient as well as the investigating physician unaware of the treatment applied.

3. RESULTS

3.1. Population

Thirty patients were included in the study. After unblinding, twenty-nine patients were finally considered: fifteen in the microkinesitherapy group (6 men and 9 women), and fourteen in the control group (7 men and 7 women). (Table 1). In the table 1, the number of patients assessed during the follow-up: among the 30 recruited patients, only 29 are analyzed, one patient never went to the second check-up. The 2 patients wrongly included have been analyzed with the others as the analysis is carried out with intention to treat. The missing patient did not present at the second check-up. Two erroneously included patients were included in the analysis with intention to treat. There was no significant difference in the patients' average age and height in both groups.

3.2 Data at the first check-up

Concerning the number of days between the trauma and the first check-up and the number of days between the two check-ups, as well as the average values of the evaluation criteria there was no significant difference between the two groups at the first check-up. The amplitudes of flexion-extension movement of the cervical spine identified during the first check-up were below the average amplitude of a standard population (125 to 129°) for both groups [16]. There is not any significant difference (unpaired t-test) between the two groups for demographic and clinical characteristics as well as evaluation criteria at the first check-up. (Table 2)

3.3 Comparison between the results of the two groups

All the results are shown in Table 3. In group 1, the patients treated with microkinesitherapy showed a statistically significant improvement of the primary endpoint, the VAS assessment of pain, and the secondary endpoint, the flexion-extension amplitude. In group 2 (control group), no significant improvement was observed, neither for the primary endpoint nor the secondary endpoint. The mean values of VAS pain and amplitude of flexion-extension movement are not statistically different (unpaired t-test) between the two groups at the second check-up. Among the symptoms assessed by the patients (vertigo, tinnitus, sleep quality,

Table 1. Studied Population

	Population included	Wrongly included*	Lost sight of**	Population analyzed
All patients	30	2	1	29
Group 1 (mk)	15	1	0	15
Group 2 (control)	15	1	1	14

*: non-traumatic pathology (1), consultation in ongoing protocol (1). **: patient absent at the second check-up (1). mk: microkinesitherapy

Table 2. Characteristics of the studied population

	Group 1 (mk) n=15	Group 2 (control) n=13	*p*
Age (years)	27.8 ± 11.0	31.0 ± 10.8	NS
Height (cm)	170.3 ± 6.0	173.6 ± 10.4	NS
men/women	6/9	7/7	
Number of days between the 1st trauma and the 1st check-up	32 ± 25	32 ± 27	NS
Number of days between the 2 check-ups	9 ± 3	8 ± 2	NS
VAS of pain at the 1st check-up	5.2 ± 2.3	4.0 ± 2.3	NS
Flexion-extension amplitude (degrees) at the 1st check-up	95 ± 29	104 ± 26	NS

Values are given as mean ± standard deviation - NS: non significant (p>0,05) by using paired t-test; mk: microkinesitherapy

Table 3. Average values for each group: of the EVA pain and of the flexion-extension's amplitude for each check-up with their evolution's comparison.

	Check-up 1	Check-up 2	p
VAS pain			
Group 1.	5.2 ± 2.3	2.5 ± 1.7	< 0.001
Group 2.	4.0 ± 2.3	3.1 ± 2.4	NS
Amplitude (degrees) of flexion-extention			
Group 1.	95 ± 29	107 ± 27	< 0.02
Group 2.	104 ± 26	107 ± 28	NS

Values are given as mean ± standard deviation - NS: non significant change between two check-up by using paired t-test

concentration, anxiety and mood,) in group 1 only sleep quality significantly changed between the two check-ups; whereas in group 2 only concentration and anxiety significantly changed between the two check-ups. The amplitudes of right-left rotation movements only improved in group 2 while the amplitudes of right-left lateral inclination movements only improved in group 1. In the Table 3 the comparison of averages using a matched data test, shows that only group 1 evolves significantly from check-up 1 to check-up 2.

4. DISCUSSION

Our study evaluates the effects of microkinesitherapy on patients suffering from post-traumatic neck pain, the main symptoms of which are pain and stiffness. Patients of both groups received the same medical treatment. Both groups showed no significant difference as regards demographic and clinical data. The conditions for achieving this double blind randomized trial allowed full compliance with the blinding of patients and the evaluating and observing physicians.

The small size of the population finishing the study may be explained by the difficulties of recruitment in the context of private practice. The reduced number of participants could have resulted in limiting the statistical strength of the tests. However, the results show a level of significance much higher than the 5% threshold retained.

The strength of this study lies on the fact that we were able to observe the effects of a microkinesitherapy session on the evolution of patients in standard practice. The choice of the assessment of pain as a primary criterion is motivated by a will to test the effectiveness of microkinesitherapy on this parameter.

The choice of the assessment of flexion-extension amplitudes as a secondary criterion is justified by the frequency of injuries affecting such movement. While the treatment had a significant effect in terms of pain and the flexion-extension amplitude in the treated group, the treatment simulation performed for the patients of the control group did not provide any significant improvement concerning pain and the flexion-extension amplitudes.

This result is in keeping with the study [17**]** showed that microkinesitherapy is effective within 8 days on functional disorders, the effect of which stabilized within the 3 following weeks [17]. These results encourage us to advise the prescription of early microkinesitherapy for this pathology.

We note that the average of the VAS was superior in group 1 than in group 2 during the first check-up. Similarly, the average amplitude of the flexion-extension movement, limited in both groups with regard to normal values [16], was inferior in group 1 than in group 2 during the first check-up. Although these differences are not significant, the superior VAS of pain and the smaller flexion-extension amplitudes for the patients of a group compared to the other one allow us to suspect a link between pain and the limitation of amplitude.

CONCLUSION

Our comparative randomized double blind trial shows the effectiveness of microkinesitherapy on post-traumatic neck pain in the population studied on two parameters: pain and flexion-extension amplitudes. From these statistically significant results, we think that microkinesitherapy is a potential adjuvant for post-traumatic cervicalgia. The relevance of this study must be put into perspective because of the reduced number of patients included. Therefore, we believe that a trial carried out under the same conditions on a larger population cohort and over a period of at least three months would allow refining of the results, particularly in relation to potential chronicity.

CONFLICTS OF INTEREST

none.

AUTHOR DETAILS

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