

Original Research

**Observational Study on Auriculotherapy in the Treatment of Chronic Musculoskeletal Pain: Preliminary Data**

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**Abstract**

**Introduction:** Pain in musculoskeletal disorders is a common problem that involves high social and individual costs. Systematic reviews and randomized controlled trials show that a number of treatments usually applied in this field are not effective. On the other hand, there is clinical evidence of the effectiveness of physical exercise, acupuncture, and auriculotherapy. Side effects of current medication limit their use.



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**Aim:** To evaluate the effectiveness of auriculotherapy on the pain of patients suffering from chronic musculoskeletal disorders (non-oncological pain)

**Methods:** From February 2010 to April 2017, in the Centre of Traditional Chinese Medicine Fior di Prugna - Local Health Unit Tuscany Centre, 1,180 questionnaires were analysed. After their first visit, where medical histories were taken and objective examinations were given, patients underwent 6 to 8 sessions of auriculotherapy once a week, according to a pre-established protocol that included the search for painful points in the ear and additional general points (functional and psychic points). Points in the ear were treated unilaterally by needles; afterwards, permanent Vaccaria seeds or press needles were applied and left in situ for a week.

The effectiveness on pain at rest and during movement was evaluated on a verbal scale via the Present Pain Intensity (PPI) and Numeric Pain Intensity Scale (NRS), self-administered before and at the end of treatment.

**Results:** Outcome indices have significantly improved. Based on the PPI questionnaire, auriculotherapy reduced pain both at rest and during movement. Patients with strong and atrocious pain decreased from 231 to 45 and 604 to 163, respectively at rest and during movement. The median value of the NRS decreased from 5 to 2 at rest and from 7 to 4 during movement.

**Conclusions:** Auriculotherapy can be effective to reduce pain in musculoskeletal disorders, in combination with usual care. Randomized controlled trials are needed to verify the efficacy of this protocol of treatment.

### Keywords

Ear acupuncture; auriculotherapy; musculoskeletal pain; integrative oncology

## 1. Introduction

Pain in musculoskeletal disorders is a common problem that involves high social and individual costs. Side effects of current medication limit their use. The current mainstay of pain management is medication, with significant side effects in the short and long-term. Characteristics ideally required for any new analgesic modality are efficacy, rapidity of administration, few side effects, minimal post-administration monitoring, improved patient satisfaction, and low cost. A novel modality such as ear acupuncture might offer a solution for these issues [1].

Systematic reviews and RCTs show that a number of treatments usually applied in this field are not effective; on the other hand, there is clinical evidence of the effectiveness of physical exercise, acupuncture and auriculotherapy [2, 3].

Auriculotherapy is a method for diagnosing and treating physical and psychosomatic dysfunctions by stimulating specific points in the ear, both with needles and pressure, and the application of Vaccaria seeds, etc. It is defined as ear acupuncture (EA) or auricular acupuncture when only needles are used. Ear stimulation involves neurological reflex, neurotransmitters, cytokines, the immune system, and inflammation. Auriculotherapy is a well-recognized technique of traditional Chinese medicine (TCM) based on long-standing tradition, but was modified and

updated by Dr. Paul Nogier in the 1950s. In TCM, the ear is connected with 12 meridians directly or indirectly, and stimulating them can restore the balance between Qi (in TCM, the circulating life force or vital energy according) and blood.

The basic pathology of pain is the obstruction of Qi and blood in the meridians, due to the invasion of pathogenic wind, cold, and dampness. According to TCM theory, if the meridians are open and the Qi and blood are circulating normally, there will be no pain; on the contrary, if they are obstructed and the flow of Qi and blood are blocked, pain will arise. When a person is invaded by external pathogens, his or her constitution can be normal or weak. If the person is weak and not able to expel these external pathogens, they will then stay in the meridians, joints, or muscles and mingle together with dampness and finally cause pain. Alternatively, when the external pathogens remain in the meridians, joints, or muscles, they will impede the Qi flow in the meridian and cause the xue flow to stagnate and phlegm to form. The stagnated xue and phlegm will further impede the flow of Qi and subsequently make the local area malnourished, causing pain. Pain is also due to internal pathogens; in fact, unbalanced emotions often affect the liver and the heart resulting in decreased Qi and blood circulation and the generation of internal wind. The underlying biological mechanism of auriculotherapy in treating pain remains elusive. One theoretical explanation is that pain and neuronal excitability are relieved by normalizing pathological, hypersensitive reflex pathways (i.e. the neural immune pathway) that interconnect the ear microsystem and the somatotopic region of the brain [4, 5]. The neurophysiological connections between ear acupoints and the human CNS have been corroborated by fMRI. The stimulation of acupoints is thought to cause vasodilative effects by releasing either beta-endorphins to elicit short-term analgesic effects or neuropeptide-induced anti-inflammatory cytokines for long-term effects [6, 7]. Considering the complex interaction between cytokines, neuropeptides, and neurotrophins pertaining to chronic pain, possible pathways of the ameliorating effect of auricular therapy on pain include: (a) the downregulation of pro-inflammatory cytokines and the upregulation of anti-inflammatory cytokines, (b) the downregulation of pro-inflammatory neuropeptides (e.g., calcitonin gene-related peptide), and (c) the downregulation of neurotrophins (e.g., nerve growth factor, NGF) [8, 9]. These responses may be modulated by inflammatory mediators and could explain the analgesic effects of auriculotherapy.

In Europe, auriculotherapy has been applied systematically and comprehensively since Paul Nogier introduced the inverted fetus map in 1957. The French version is based on the assumption that the human body is represented in the outer ear as an inverted fetus and that there is a relationship between distinctive anatomical sites and specific points in the ear. Previous studies showed that EA is effective to reduce pain as a single treatment or as an adjuvant of other types of treatment. Various methods currently existing for ear stimulation include needles, seeds, magnetic stones, lasers, ultrasound, bloodletting, moxibustion, electric treatment, and pressure by hands [10-14].

As to the efficacy of EA in patients suffering musculoskeletal pain, in 2014 Yeh et al. [15] performed a meta-analysis of pain score reduction, using ear acupuncture for acute (7 trials) and chronic (6 trials) pain in a variety of comparator groups and settings. The researchers concluded that EA is useful as an adjunct therapy for pain management. This conclusion was based on a meta-analysis of 13 randomized controlled trials (RCTs), totalling 806 patients with a mixture of

pain types. The researchers reported a standardized mean difference in pain reduction of 1.59, indicating a large effect size.

In a RCT Yeh et al. [16] used Auricular Point Acupressure (APA) to manage chronic low back pain (LBP) in 61 participants randomized into either a real APA or sham APA treatment group once a week for 4 weeks. Among participants in the real APA group, there was a 30% reduction of worst pain after the first day of APA treatment, and continuous reduction in pain (44%) was reported by the completion of the 4-week APA. This study shows that APA is a promising and not invasive pain management strategy that can be self-managed by patients for chronic LBP. Findings suggest that APA treatment affects pain intensity through modulation of the immune system, as reflected by APA-induced changes in serum inflammatory cytokine and neuropeptide levels [17]. A systematic review and meta-analysis of 15 trials showed that auriculotherapy decreased pain intensity, especially for chronic low back pain and chronic tension headache and was a promising intervention for chronic pain relief [18].

A RCT on eighty adults with LBP and pain intensity equal to or higher than 4 (on a 0-10 scale) randomly allocated (1:1) to either a EA group or a placebo group revealed that EA is better than a placebo to reduce pain [19]. A review and meta-analysis of 7 trials showed an encouraging effect of auricular acupressure in improving pain in patients with chronic low back pain [20]. A recent review [3] of 14 reviews on the management of insomnia, smoking cessation, and pain, within the clinical scope of Neurology, Orthopaedics and Rheumatology, concluded that auriculotherapy has positive effects associated with conventional treatments of insomnia and acute and chronic pain (mainly headaches, migraines, back pain, neck pain, and osteoarthritis).

Auriculotherapy has very few adverse effects (AE). In 2014 a systematic review [21] on 32 RCTs, five uncontrolled clinical trials, four case reports and two controlled clinical trials reported that the most frequent adverse effects related to auricular acupuncture were tenderness or pain at insertion, dizziness, local discomfort, minor bleeding, and nausea.

For auricular acupressure, local skin irritation and discomfort, mild tenderness or pain, and dizziness were commonly reported. Skin irritation, local discomfort, and pain were detected in auricular electroacupuncture, and minor infection was identified in auricular bloodletting therapy.

Most of these events were transient, mild, and tolerable; no serious adverse event was identified. Preliminary evidence provides that EA is a relatively safe approach.

## **2. Aim**

This study intended to evaluate the effectiveness of auriculotherapy on the pain of patients suffering from chronic musculoskeletal disorders (non-oncological pain).

## **3. Materials and Methods**

This interventional observational study was conducted at the Centre of Traditional Chinese Medicine “Fior di Prugna,” a public outpatient clinic of the Tuscan healthcare system. From February 2010 to April 2017, 1,180 questionnaires were analysed.

The analysed sample was composed of 835 females and 345 males, with mean age of 65.7 years and median age of 68.

Medical doctors in collaboration with non-medical health professionals trained at the TCM School of Florence conducted the auriculotherapy sessions. The participants were informed about

the type of treatment applied and they all signed consent forms. After the first visit, which included reporting of medical history and an objective examination, patients underwent 8 sessions of auriculotherapy once a week for 8 consecutive weeks (from 1/2/2010 to 31/12/2012) and 6 sessions from January 2013 to April 2017, assuming that six weeks were sufficient to get a positive result.

Assessment of pain was performed at the beginning and at the end of treatment (with self-administered questionnaire PPI/NRS) at rest and during movement. The PPI (Present Pain Intensity) is a verbal scale ranging from absence of pain to terrible pain [22]; the NRS (Numeric Rating Scale) is a numeric scale and ranges from 0 (no pain) to 10 (the worst pain imaginable) [23-25].

### **3.1 Therapeutic Protocol**

After examining and palpating the patients, the therapeutic protocol included the search for painful points of the antihelix, helix, fossa anthelicis and navicular fossa areas of the ear (corresponding to the spinal column and limbs). Specifically, functional points (1<sup>st</sup> and 2<sup>nd</sup> level) are used such as 0 point, shen men, myorelaxant, thalamus and psychic points (anxiolytic and/or antidepressant), and points corresponding to areas of pain (for example shoulder, knee, and foot points).

The painful points in the ear (no more than 7) were treated unilaterally on the painful side, or if the pain was central, on the patient’s dominant side by needles (13 mm x 0.25 mm) left in situ for 20 minutes. Afterwards, permanent Vaccaria seeds or press needles were applied and left in situ for a week. Blue press needles (1.2 mm) were chosen for points corresponding to the painful areas whereas the finest green press needles (0.9 mm) were used for the functional points of the 1<sup>st</sup> (shen men, 0 point) and 2<sup>nd</sup> level (thalamus, myorelaxant, anxiolytic and antidepressant).

Vaccaria seeds were applied instead of press needles on cardiac patients or those on anticoagulant therapy. In between treatments, patients were asked to stimulate points where the patches were inserted 3 or 4 times a day for 15/20 pressure per point. The day before the treatment, the patient removed the patches. Any adverse events of the therapy was recorded in the specially prepared form.

### **3.2 Demographic Characteristics of Patients**

The sample (Table 1) was composed of 1,180 patients: n = 835 females (71%) and n = 345 males (29%).

**Table 1** Patients' Ages.

<b>Age</b>	<b>Male</b>	<b>%</b>	<b>Female</b>	<b>%</b>	<b>Total</b>	<b>%</b>
18-40	21	6.1	23	2.7	44	3.7
41-55	56	16.2	146	17.5	202	17.1
56-70	144	41.7	299	35.8	443	37.5
≥ 71	124	3.9	367	44.0	491	41.6
Total	345		835		1,180	

Out of a total of 1,180 patients, the mean age was 65.7 years and the median age 68, with a range between 23-92 age years. Specifically, the mean age for women was 66.4 years, with a median age of 69; for men, the mean age was 64.2 years, with a median age of 66.

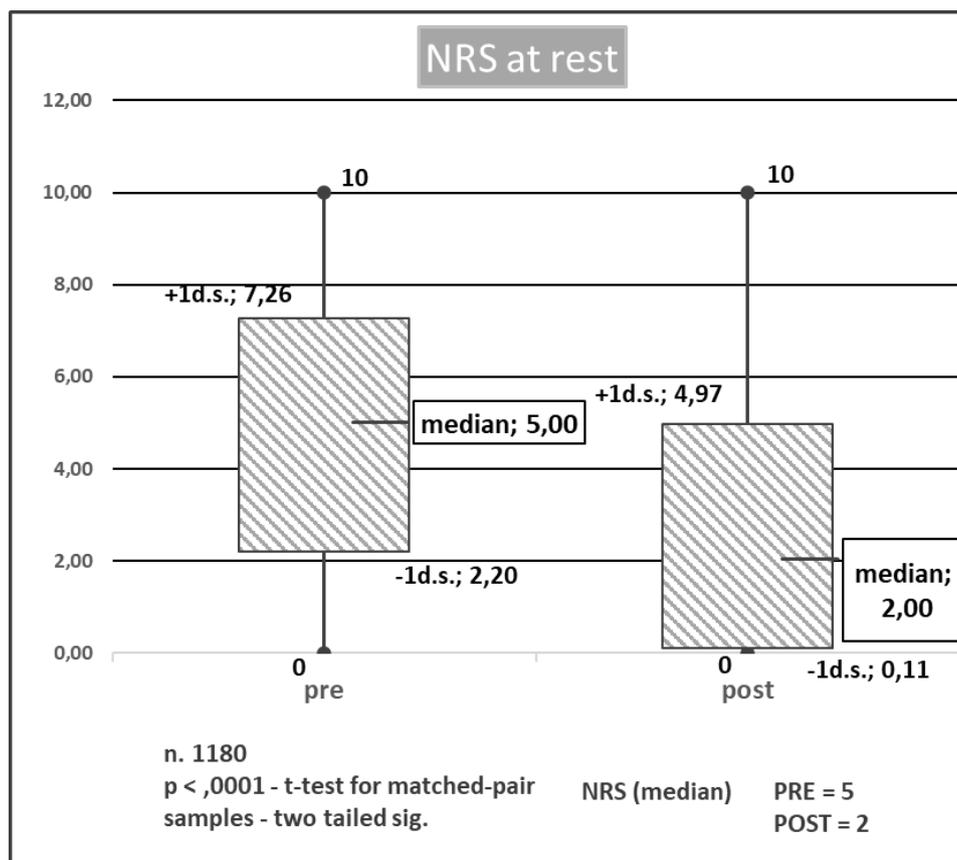
As described in Table 1, the age of our patients was quite high, as the majority of them were older than 70 years.

#### 4. Statistical Analysis

Statistical analyses were performed using the statistical software package PASW (release 18.1 of SPSS, Statistical Package for Social Sciences). Outcome evaluation of the NRS scale was conducted via t-test applied to matched-pair samples, associated with a two-tailed significance test.

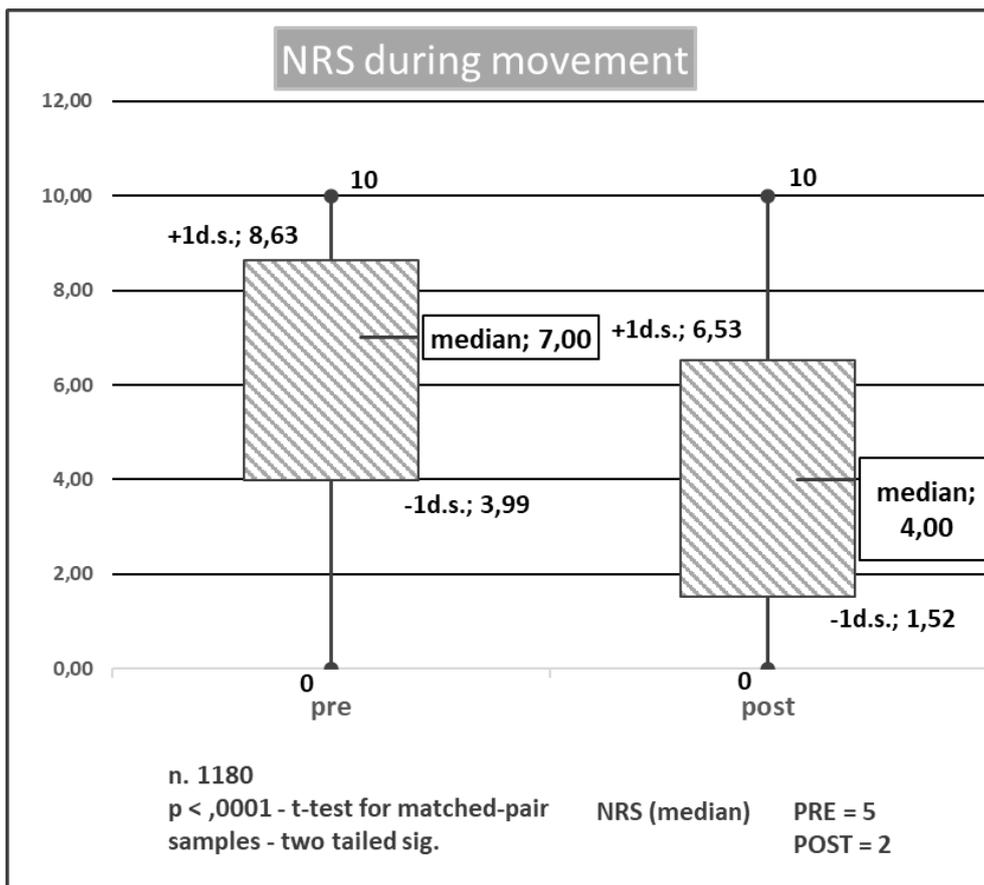
#### 5. Results

Data processing is still ongoing, and only preliminary data are reported in the following tables and figures. Preliminary data shows that outcome indices have significantly improved. Based on the PPI and NRS questionnaire, auriculotherapy reduced pain both at rest and during movement. The median value of the NRS decreased from 5 to 2 at rest with a reduction of 60% (Figure 1).



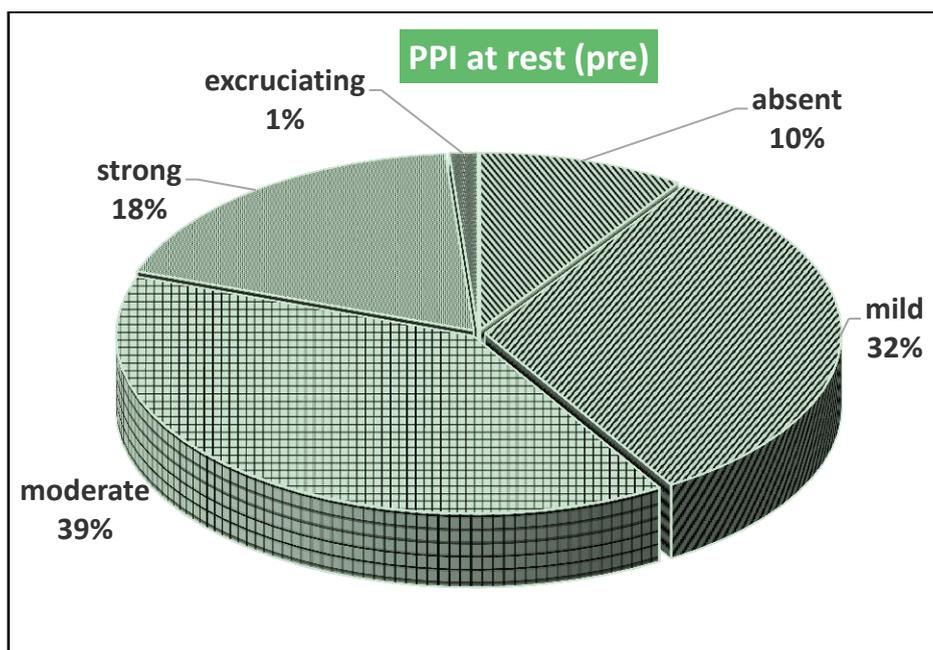
**Figure 1** NRS pre and post-treatment at rest.

The median value of the NRS also decreased from 7 to 4 during movement with a reduction of 42.9% (Figure 2).



**Figure 2** NRS pre and post-treatment during movement.

Patients experiencing strong and excruciating pain at rest decreased from 231 to 45 (a reduction from 19% to 4%). The number of patients without pain increased from 111 to 407 (from 10% to 35%), as described in Table 2 and Figure 3.



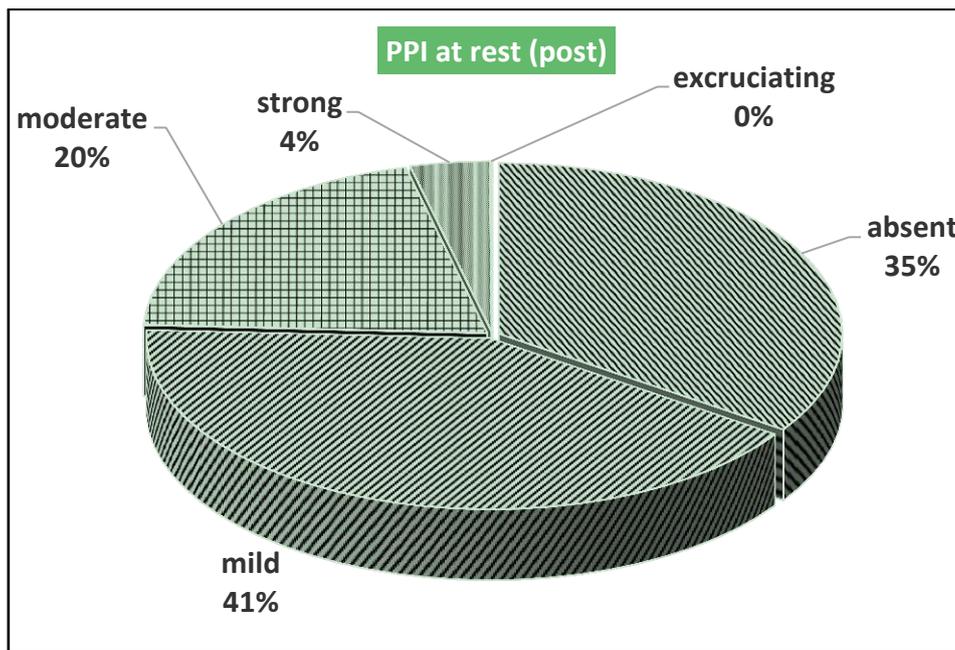
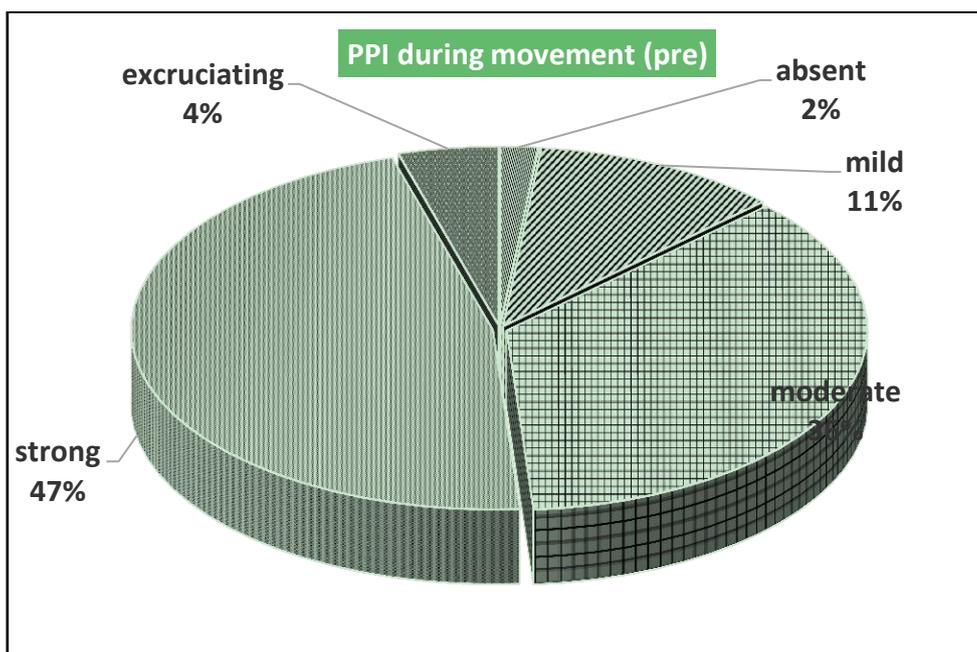


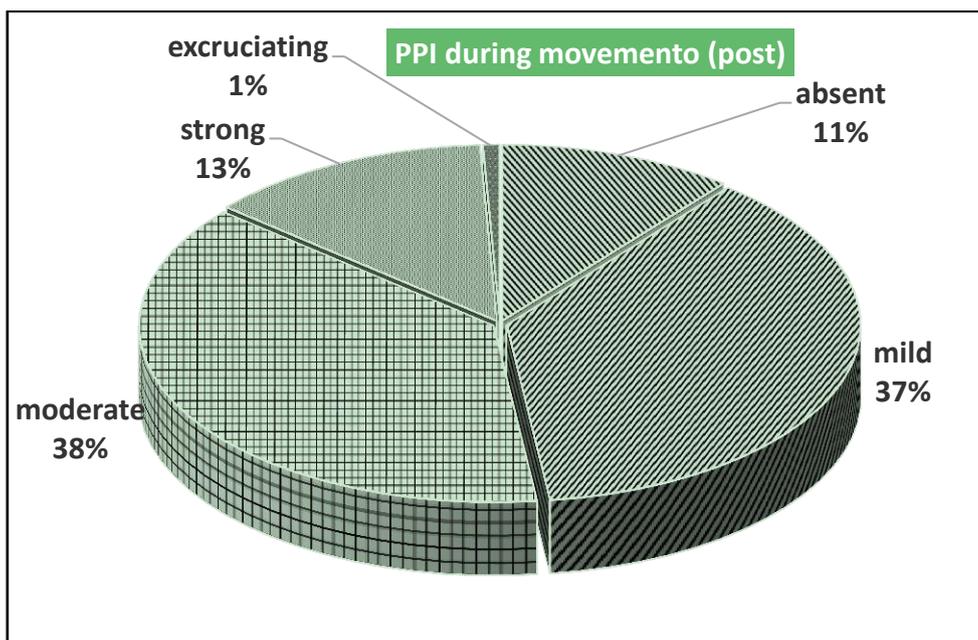
Figure 3 PPI at rest - percentage of patients.

Table 2 PPI at rest - number of patients.

	Absent	Mild	Moderate	Strong	Excruciating
Pre	111	376	462	216	15
Post	407	487	241	44	1

Patients experiencing strong and excruciating pain during movement decreased from 604 to 163 (from 51% to 14%). Patients without pain increased from 20 to 127 (from 2% to 11%) as described in Table 3 and Figure 5.





**Figure 4** PPI during movement - percentage of patients.

**Table 3** PPI during movement – number of patients.

	Absent	Mild	Moderate	Strong	Excruciating
<b>Pre</b>	20	131	425	551	53
<b>Post</b>	127	440	450	154	9

No relevant adverse events were reported except for two episodes of dizziness resolved immediately without consequences and sporadic episodes of pain at the points of needle insertion.

## 6. Bias

The main limitation of the study was the lack of a control group. As the study did not have a placebo-control group, we were not able to differentiate the true effects of auriculotherapy from the possible psychological effects linked to the patients’ expectations.

Another limitation was the absence of follow-up, so we could not explore any benefits of the treatment in the longer term. Studies on the sustained effects of auriculotherapy for pain relief are varied and report findings ranging from the immediate up to 6 months. However, these findings are limited by small sample sizes [15]. Furthermore, the studies did not analyze the location of the pain.

## 7. Discussion

The therapeutic protocol applied is in line with studies published in the literature [14, 20].

Due to the design of this observational study, the results cannot be compared with the case-control studies reported in the literature. However, the values of improvement were higher than those reported in previous studies [16, 18, 19] and the data obtained was significant, especially

considering that 41.6% of the patients were older than 71 years of age, and affected by multiple longstanding diseases and widespread pain syndromes. The outpatient clinic where the study was performed is included in Tuscany's public healthcare service, and older, low-income patients can access it easily free of charge.

In a meta-analysis [15], the treatment duration for chronic pain varied from a one-time treatment to up to six treatments. The lack of agreement on the optimal duration of auricular therapy may mean that some patients do not receive the best treatment. In general, 2 to 10 weeks of auricular therapy was reported to provide treatment benefits; however, these reports lack empirical evidence. Data are preliminary but we will be able to connect results and duration of treatment after further data processing. This will allow us to compare patients who underwent either a six-session (n = 957) or eight-session cycle (n = 223).

Adverse effects experienced during the study period were minor, in line with other reports in the literature [14, 16, 20].

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### **Author Contributions**

Cortesi EB. and Monechi MV. drafted the manuscript and contributed to analysis and critical interpretation and bibliographic research; Baccetti S. conceived the survey and analyzed the results; Cucca B. registered the data of questionnaires, drafted tables and figures and co-ordinated the authors; Di Stefano M. participated in the critical revision of the manuscript and data; Picchi M. made the statistical analysis; Conti T., Traversi A., Terranova F., Montelatici R., Barberousse SY., Sabatini F., Vuono C., Bini C. widely contributed to data collection. All the authors participated in the final revision of the article.

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### **Competing interests**

No conflict of interest.

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