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International Journal of Pharma Sciences and Scientific Research

ISSN 2471-6782

Research Article Open Access

How do the number and the duration between osteopathic treatments influence the effect on patients suffering from foot-related pain? A dose-response study

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Citation: Joachim Kaufmann et al, (2016) How do the number and the duration between osteopathic treatments influence the effect on patients suffering from foot-related pain? A dose-response study. Int J Pharm Sci & Scient Res.2:5, 209-216

Received November 3, 2016; **Accepted** November 12, 2016; **Published** November 25 2016.

Abstract

Aim: To determine the combination of the "number of treatments" and the "interval between treatments" in order to optimize the osteopathic treatment effect on foot-related pain.

Material & Methods: The material consists of 32 female and 22 male patients with a mean age of 42 years (SD =13.1) and BMI of 27.0 (SD =4.4). Ten patients reported injury on the left side, 17 patients on the right side, and 27 patients suffered on both sides. The study was performed as an observer blinded, randomized single center trial with 3^2-factorial design. The factors used were "number of treatments" and "treatment intervals". Patients were allocated to treatment groups by nested block randomization with a fixed block size of 18 and 6, respectively. "Pain at rest" and "pain at load" were recorded on a 10 cm Visual Analog Scale before, one day after final treatment, and 4-week follow-up.

Results: Four treatments with 7-day intervals were found to be the superior combination for reducing pain at rest. Significant reduction in pain at rest was obtained in all groups given four treatments. Both the 7-day and 10-day interval groups reported a significant reduction in pain at load after receiving four treatments and the 10-day treatment interval found to be the optimal combination. Number of treatments seemed to be the dominant factor, but the treatment intervals played an important role. An increase in the number of treatments recommended an increased duration between treatments in order to obtain effective and significant pain reduction.

Conclusion: The most significant reduction in pain at rest and at load occurs after four treatments administered at 7- and 10-day intervals, respectively.

Keywords: Osteopathic treatment, Foot-related pain, Dose-response, 3^2-factorial design, Number of treatments, Duration between treatments

Introduction

Background. More than two-thirds of all visits to a general healthcare practitioner (GHP) are related to musculoskeletal pain (1). Only the back and the neck discomfort involves in more patient complaints than foot-related problems (2). The risk factors seem to be increased age, gender, obesity, and pain in other body regions (3), such as the knee (29.1%), hip (33.4%), and back (26.6%). GHP's have to ask themselves if it is sufficient only to investigate for and treat local foot problems.

The foot is a part of a biomechanical chain. This either occurs via the ground floor, with the pain in one foot leading to overload of the other foot or decreased movement from structures above, such as increased tone of muscles or fascia (4). The treatment area depends on the location of decreased movement in relation to the complaint. The area of pain is a consequence and not necessarily

the primary treatment area (5). One of the osteopathic principles is to find the cause of decreased movement, fix the problem by increasing the movement, and then leave it alone and allow the body to integrate the new movement of the restrictive area into the global mobility. This has been the predominant philosophy in osteopathic medicine since the 1940s (6).

The most common movement-related foot conditions are plantar fasciitis related to inferior heel pain (7, 8), Achilles tendinitis, which leads to rear foot conditions (9), ankle twisting (10), and osteoarthritis of the ankle that leads to degenerative disease of the foot (11).

Dose-response studies are required documentation from the pharmaceutical industry for all new drugs in order to optimize the treatment effect with lowest frequency and degree of adverse events (AE) (12, 13). Manual therapists with their knowledge of the human body and treatment techniques tend to dose their treatment based on what they have learned through a combination of education and own clinical experience. Few evidence-based dose-response studies conducted in the manual field (14, 15). Existing guidelines for foot complaints differ from no treatment to 6 treatments twice a week and 16 times in 4 weeks (16, 17, 18). In order to avoid under- and overdosing in the manual therapeutic area, it is necessary to perform dose-response studies to obtain evidence-based guidelines for treatment of different complaints.

In all kinds of manual therapy, the treatment dose consists of both the number of treatments given and the duration between each intervention. In accordance with osteopathic philosophy, the body is a self-regulating system (19), and the duration between each intervention is of utmost importance. The duration must be long enough for the body to regulate itself without disturbance of the next intervention, but short enough for self-regulation impulse. In order to obtain a sufficient effect while avoiding overload of the body, the total number of interventions has a lower and an upper limit. The number of treatment may interact with the duration between treatments and has to be investigated.

A commonly used method of evaluating pain severity and relief is the visual analog scale (VAS) (20). VAS is an easily used method that provides reproducible results (21). Measurement of pain by VAS is recommended because the method is sensitive enough to detect treatment effects (22) and quantification of pain is one of the main factor in foot complaints.

Ischemia of the lower limbs affects between 12 and 14% of the general population. The majority of patients are asymptomatic, and one-third of patients are under-diagnosed (23). In order to investigate possible relationships between the foot conditions and decreased arterial blood flow, the ankle-brachial index (ABI) has to be investigated (24).

The aim of the present study was to determine the combination of "number of treatments" and "duration between treatments" optimizing the effects of osteopathic manual treatment (OMT) of foot-related pain at rest and load.

Material and Methods

Population and study material. The study population consisted of patients of both genders between 18 and 65 years of age suffering from pain related to Achilles tendinitis, plantar fasciitis, ankle sprain, or arthritis of the ankle. Patients with pain scores less than 2.5 cm on a 10 cm VAS (16) and patients under medical treatment for pain were excluded. Thirty-two female and 22 male patients with foot-related pain with a mean age of 42 years (SD =13) and BMI of 27.0 (SD = 4.4) were equally allocated to nine treatment groups defined by "number of treatment" and "duration between treatments" (Fig.1). No significant differences detected between the groups with regard to diagnoses and side of injury (Table I),

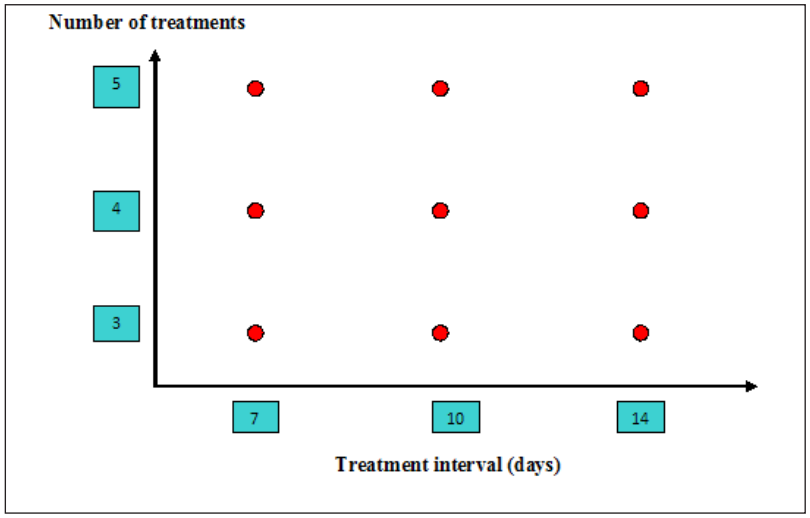

Figure 1: 3^2 factorial design with "number of treatments" and "treatment intervals" used as the two factors. Number of patients within each group is given in the circles

Treatment Groups		Diagnoses				
Number of treatments	Distance between treatments	Twisted ankle	Achilles tendinitis	Plantar fasciitis	Arthritis	Total
3	7	3	5	2	0	6
	10	0	5	2	0	6
	14	1	3	1	1	6
4	7	2	2	3	0	6
	10	3	2	2	0	6
	14	2	4	3	2	6
5	7	2	3	5	0	6
	10	1	3	4	0	6
	14	1	1	4	1	6
Total		15	25	26	4	54

Table I: Treatment Groups and Diagnoses

Treatment Groups		Demographic Factors			
Number of treatments	Distance between treatments (days)	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (kg/m^2)
3	7	46.5 (11.4)	88.3 (20.7)	178.8 (11.4)	27.2 (3.7)
	10	36.5 (8.2)	74.7 (10.9)	166.7 (3.4)	26.8 (3.3)
	14	44.2 (15.0)	72.3 (14.4)	168.2 (7.8)	26.0 (7.1)
4	7	35.7 (10.2)	88.5 (10.5)	179.3 (12.6)	27.8 (4.4)
	10	52.0 (13.9)	90.3 (14.8)	175.3 (7.6)	29.7 (6.4)
	14	47.0 (12.0)	78.3 (10.1)	172.0 (9.6)	26.4 (2.0)
5	7	30.3 (11.6)	73.3 (8.8)	168.5 (9.2)	25.8 (2.2)
	10	41.7 (16.4)	74.3 (14.2)	170.8 (6.5)	25.5 (4.3)
	14	45.2 (10.3)	93.3 (21.0)	178.7 (11.9)	28.3 (4.9)

Table II: Treatment Groups and Demographic Factors

gender, age, weight, and height (Table II). The groups were clinically comparable.

Study design. The study was performed as an open, randomized single center trial with a 3^2-factorial design (25, 26). "Number of treatments" and "duration between treatments" used as the two factors (Fig.1). The selected levels for "number of treatments" were 3, 4, and 5, and for "treatment intervals", 7, 10, and 14 days. The patients were allocated to treatment groups by nested block randomization, with a fixed block size of 18 and 6, respectively (27, 28).

Study procedure. The patients were recruited from orthopedic clinics and GHPs in Bergen, Norway. Patients fulfilling the inclusion without meeting the exclusion criteria and willing to provide informed consent for participation were allocated at the osteopathic clinic in which all trial treatment was performed.

The GHP and the responsible osteopath verified whether the patients fulfilled the inclusion and exclusion criteria. The areas of somatic dysfunction identified and documented by palpation, distinguishing tender spots, asymmetric bony landmarks, restricted joint motion, and abnormal tissue texture.

In accordance with the pre-randomization key, standardized OMT with a duration of 40 minutes as described below was given all the patients. The regional ethical committee in western Norway approved the study.

Osteopathic treatment procedure: High-velocity low-amplitude (HVLA) techniques, springing techniques, muscle energy

techniques, soft tissue techniques, functional techniques, strain-counter strain techniques, facilitated positional release, Still techniques, cranial osteopathy, and lymphatic techniques (29) were used to increase the movement of restrictive structures . In cases of rigid feet, the responsible osteopath developed a procedure based on the following principles: 1) treatment from the surface to the depth; 2) from low to high-impact techniques; and 3) from slow movements to HVLA.

Variables: The patient recorded the intensity of pain at rest and at load on a 10 cm VAS (30) just before each treatment, one day after the last treatment, and 4-weeks follow-up. Additionally, systolic blood pressure was measured on both upper arms and ankles simultaneously, from which the ABI were calculated (31).

Statistical Analysis: All assumed continuously distributed variables expressed as mean value with 95% confidence intervals constructed using the Student procedure (27). As an index of dispersion, the standard Deviation (SD) is given.

All tests performed two-tailed and differences classified significant for p-values less or equal to 5%. Analysis of Covariate (ANACOVA) with the second design factor and the pretreatment value used as covariates (32).

Results

Number of treatments corrected for duration between treatments: The reduction in pain at rest was significant ($p < 0.01$) in all three groups from baseline to one day after the final treatment (Fig. 2a). This was most pronounced in the groups receiving 3 - 4 treatments. For the group receiving three treatments, the pain was reduced from 3.7 (95% CI 2.6 - 4.8) to 2.5 (95% CI 1.5 - 3.6) the day after end of treatment. In the group receiving four treatments, a similar reduction from 3.3 (95% CI 1.9 - 4.7) to 1.7 (95% CI 0.7 - 2.7) was found. Pain at rest was reduced from 3.0 (95% CI 2.2 - 3.7) to 1.8 (95% CI 1.1 - 2.4) in the group receiving five treatments.

A similar pattern was detected for pain at load, with significant ($p < 0.01$) reductions in all three groups (Fig. 2b). The pain at load was reduced from 6.0 (95% CI 5.3 - 6.6) at baseline to 3.1 (95% CI 1.8 - 4.3) in the group receiving three treatments. In the group receiving four treatments, the pain was reduced from 5.7 (95% CI 4.7 - 6.8) to 3.1 (95% CI 1.9 - 4.4), and from 5.6 (95% CI 4.8 - 6.2) to 3.6 (95% CI 2.3 - 5.0) for patients in the group receiving five treatments. For both pain at rest and at load, 3 – 4 treatments was superior to five treatments (Figs. 2a and b).

Duration between treatments corrected for number of treatments; Pain at rest was significantly reduced ($p < 0.01$) in all groups related to the duration between treatments (Fig. 3a). In the group with 7-day treatment intervals, pain at rest was reduced from 2.9 (95% CI 1.8 - 4.0) to 1.4 (95% CI 0.5 - 2.3) the day after the end of treatment. By increasing the interval duration to 10 days, the pain at rest was reduced from 2.9 (95% CI 1.8 - 2.8) to 1.7 (95% CI 1.0 - 2.3), and the pain was reduced from 3.7 (95% CI 2.7 - 4.7) to 2.4 (95% CI 1.4 - 3.3) in the group treated at 14-day intervals. For pain at rest, seven days between treatments seemed to be the superior choice.

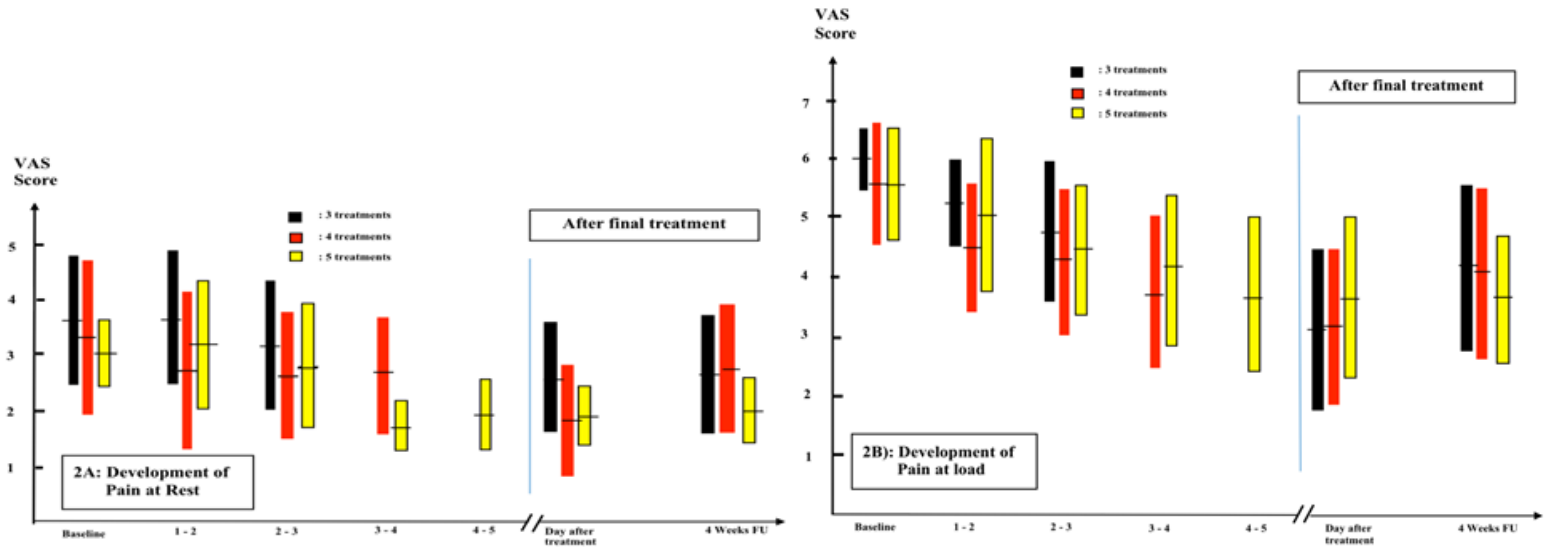

Figure 2: Development of pain at rest 2A) and at load 2B) related to "number of treatments" during the study and after 4 weeks of follow-up

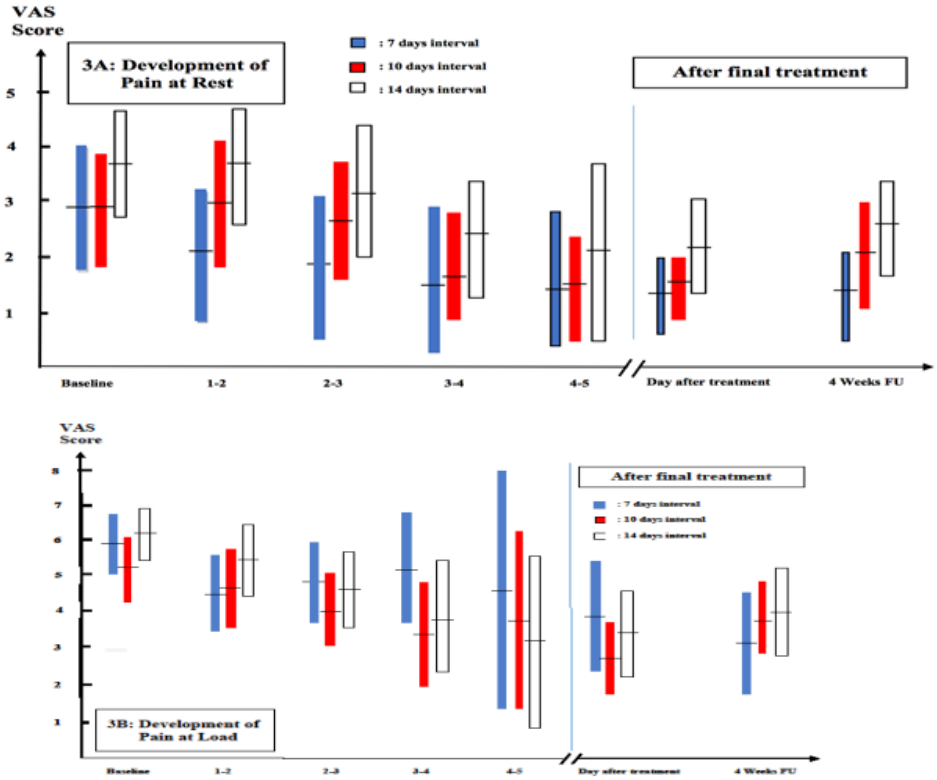

Figure 3: Development of pain at rest 3A) and at load 3B) related to "duration between treatments" during the study and after 4 weeks of follow-up

Pain at load was significantly ($p < 0.01$) reduced in all three groups (Fig. 3b). In the 7-day treatment interval group, pain at load was reduced from 5.9 (95% CI 5.0 - 6.7) at baseline to 3.9 (95% CI 2.5 - 5.3) one day after the end of treatment. When increasing the duration between treatments to 10 days, the pain at load was reduced from 5.2 (95% CI 4.2 - 6.0) to 2.7 (95% CI 1.7 - 3.7), whereas increasing the interval to 14 days resulted in a reduction from 6.2 (95% CI 5.4 - 6.7) to 3.5 (95% CI 2.1 - 4.8). Ten and 14-day treatment intervals was superior to 7-day intervals regarding reduction in pain at load.

Interaction between "number of treatments" and "duration between treatments": Four treatments with 7-day treatment intervals was the superior combination for reducing pain at rest (Table III). Four treatments resulted in significant reductions of pain at rest in all groups related to the duration between treatments. The number of treatments seems to be the dominant factor for reduction of pain at rest.

Four treatments with 10-day treatment intervals were the optimal combination for reducing pain at load (Table III). The study showed an interaction between these two factors. An increase in the number of treatments with an increased interval between treatments is recommended in order to maintain significant pain reduction. The results indicate a positive correlation between the two factors regarding reduced pain at load.

AB-Index: The resting ABI on both sides was found to be within the normal range for all the patients before inclusion in the study. No significant changes in the indices were detected during treatment and after 4 weeks of follow-up.

Discussion

The severity of pain recorded on the 100 mm VAS classifies as "Mild" for pain ≤ 30 mm, "Moderate" for scores of 31 to 69 mm, and "Severe" for scores ≥ 70 mm (33). In accordance with this definition, all the included patients in the present study initially classifies as "Moderate" or "Severe" pain at load. The majority of the patients related to pain at rest classifies as "Moderate". The clinical importance of pain relief is the main item in several studies. A pain reduction less than 13 mm on a 100 mm VAS classifies of no clinically importance in some cases (34). Others suggest the limit to be between nine and 14 mm (35, 36). The mean reduction of pain both at rest and at load during the osteopathic manipulative treatment (OMT) treatment were significant and larger than 14 mm in all the nine treatment groups.

Foot pain at rest and at load is usually different. Pain related to decreased circulation gets better with movement (37), and pain related to inflammation and overload reduces by rest (38, 39). In order to investigate the effects of OMT, it is of the utmost importance to study the pain in both situations.

Number of treatments	Duration between treatments (Days)					
	Pain at rest			Pain at load		
	7	10	14	7	10	14
3	32.7	30.8	22.6	56.0	47.4	45.1
	-47.3 – 112.7	-8.7 – 70.3	-33.3 – 78.6	17.2 – 94.7	19.6 – 75.3	-7.4 – 97.6
4	75.9	57.9	50.9	39.4	74.7	38.0
	45.8 – 106.0	27.0 – 88.9	17.6 – 84.2	7.7 – 71.2	55.1 – 94.3	-2.6 – 78.7
5	44.2	48.9	23.2	18.4	32.6	45.1
	-3.3 – 91.7	23.6 – 74.1	-49.6 – 96.1	-49.3 – 86.1	-12.9 – 78.1	-4.3 – 94.5

Table III: Pain reduction from baseline to end of treatment in percent related to "number of treatments" and "duration between treatments". The results are expressed as mean values with 95% confidence intervals.

The effect of OMT consists of three parts. In addition to the treatment content, the numbers and the duration between each treatment influences the effect. In the present study, the content of each OMT was kept constant, but the number and duration between treatments varied. The effect of OMT treatment is expected to increase with increasing numbers but may obtain an optimal effect level after a given number of treatments.

Number of treatments: In the present study, four treatments was the superior number with regard to immediate effect. Both three and five treatments demonstrated significant effects, but less compared to four. Three treatments did not seem sufficiently to influence the structures involved and did not obtain resolution of the problem. By performing five or more treatments, the effect reduces compared to four treatments. This was not in accordance with the expected development. It seems to result in an overload of the structures involved, indicating that the dose might be too high.

The present results indicate that the effect increasing with increasing number of treatment; obtaining a maximum effect by four treatment and then reduces again with higher number. Three or lower number of treatments might not involve the structures sufficiently, and five treatments or more seem to overload the body. The mechanism of OMT action might probably involve response from the immune system.

Duration between treatments: The decrease in pain at rest was largest and most stable with 7-day treatment interval group. May be the structures involved required the shortest duration between the interventions. However, the baseline pain in the treatment groups with seven and 10-day intervals was less compared to the 14-day interval group. Reduced irritation of the structures involved allows patients to tolerate a shorter duration between treatments.

The reduction of pain at load was lowest with a 7-day treatment interval. Regarding pain at load, this interval may be too short and irritate the involved structures. By increasing the interval, the structures became more responsive to new treatment. Intervals of 10 and 14 days give the body better time to recover. The present study indicate that the optimal duration between treatments of pain at load may be between 10 and 14 days.

Combination of number of treatments and duration between treatments: The largest reduction in pain at rest occurred with four treatments and 7-day treatment interval. With lower pain level at rest, seven days interval might be sufficient in order to recover the involved structures. The shortest interval duration in this study is seven days. A shorter interval may even increase the OMT effect on pain at rest.

Four treatments with a 10-day interval gave the largest effect in pain reduction at load. The increase in the treatment interval from pain at rest to pain at load may be due to the difference in structural irritation involved. The baseline pain at rest was lower compared to pain at load. Pain at load may reflect more irritation of the structure. A 7-day treatment interval may be too short for the structures to recover. However, an increase in treatment intervals to 14 days may be too much. The effect from one treatment to the next reduces, and the new treatment is not able to maintain the previously obtained effect.

The present results indicates that an increase in the number of treatments demands an increased treatment interval in order to optimize pain reduction.

The largest reduction in pain at rest and load occurred with four treatments. The power of the study would have increased if the duration between treatments had more differentiations. Such differentiations requiring for an n2-factorial design with n>3 and resulting in a larger number of patients. A better solution will be to change the factorial design to a "Response Surface Pathway" design (RSP). Such a design will obtain result that is more exact with a low number of patients (40).

Conclusion: The number of treatments and the duration between treatments significantly influences the OMT effect. The two factors correlates resulting in a significant interaction, but the number of treatments seems to be the dominant factor. The optimal

combination for pain at rest seems to be four treatments with a 7-day interval and four treatments with a 10-day interval for pain at load.

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