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ORIGINAL ARTICLE

The effect of dry needling in the treatment of myofascial pain syndrome: a randomized double-blinded placebo-controlled trial

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Abstract The objective of this study was to test the hypothesis that dry needling is more effective than sham dry needling in the treatment of myofascial pain syndrome (MPS). This was a prospective, double-blinded, randomized-controlled study conducted in an outpatient clinic. Thirty-nine subjects with established myofascial trigger points were randomized into two groups: study group (N=22) and placebo group (N=17). Dry needling was applied using acupuncture needles, and sham dry needling was applied in the placebo group. The treatment was composed of six sessions which were performed in 4 weeks; the first four sessions were performed twice a week (for 2 weeks) and the last two, once a week (for 2 weeks). The visual analog scale (VAS) and Short Form-36 (SF-36) were used. When compared with the initial values, VAS scores of the dry needling group following the first and sixth sessions were significantly lower (p=0.000 and p<0.000, respectively). When VAS scores were compared between the groups, the first assessment scores were found to be similar, but the second and third assessment scores were found to be significantly lower in the dry needling group (p=0.034 and p<0.001, respectively). When SF-36 scores of the groups were compared, both the physical and mental component scores were found to be significantly increased in the dry needling group, whereas only those of vitality scores were found to be increased significantly in the placebo (sham needling) group. The present study shows that the dry needling treatment is effective in relieving the pain and in improving the quality of life of patients with MPS.

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Keywords Dry needling · Myofascial pain syndrome · Pain · Quality of life

Abbreviations

MPS	Myofascial pain syndrome
RCTs	Randomized clinical trials
VAS	Visual analog scale
QoL	Quality of life

Introduction

Myofascial pain syndrome (MPS) is a common form of pain that arises from muscles or related fascia. It is usually associated with myofascial trigger points (MTrP) which are highly localized, hyperirritable spots in a palpable, taut band of skeletal muscle fibers [1]. MPS has been also described as a common cause of pain (especially musculoskeletal pain) in clinical practice [2, 3]. The prevalence of MPS varies from 21 to 85 % among individuals with regional pain complaints [4].

Physical therapy, exercise, ischemic compression (a therapy technique where blockage of blood in an area of the body is deliberately made so that a resurgence of local blood flow will occur upon release) heat, stretch and spray technique, acupuncture, local injections, and pharmacological treatments are all used for management of MTrPs [5]. Among those, trigger point injection is one of the most effective methods [6, 7]. It is performed by needling directly into the MTrP; with or without injection of saline, local anesthetic, corticosteroid, and botulinum toxin. After Lewit proposed that the needling effect is distinct from that of the injected substance [8], dry needling method has been used more commonly than before. In numerous randomized clinical trials (RCTs) and one systematic review, no difference

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was found between the effects of injections with different substances and those of dry needling in the treatment of MTrPs [9–11].

The principal goal of this study was to assess the efficacy of dry needling treatment in patients with MPS. In this study, we used a strict technique and defined the exact places of needle insertion which can be thought to be the main superiority of the study.

Methods

Study design

The study was designed as a double-evaluator and subject-blinded, randomized, controlled trial in which dry needling and sham dry needling are compared. The study protocol was compatible with the declaration of Helsinki and approved by the Local Ethics Committee. Before the study, oral and written informed consents were obtained from each subject.

Participants

Thirty-nine patients with MPS were consecutively recruited over a 6-month period between January and June 2011 in our center (Fig. 1). Subjects were included in the study if they fulfilled the following criteria: presence of at least one active trigger point, age between 24 and 65 years, and symptom duration ≥6 months.

MPS diagnosis was made according to Travell and Simons' criteria [1] whereby five major and at least one minor criteria are required for clinical diagnosis (Table 1).

Table 1 MPS diagnostic criteria according to Travell and Simons [1]

MPS diagnostic criteria	
Major criteria	
1.	Localized spontaneous pain
2.	Spontaneous pain or altered sensations in expected referred pain area for given trigger point
3.	Taut, palpable band in accessible muscle
4.	Exquisite, localized tenderness in precise point along taut band
5.	Some measurable degree of reduced range of movement
Minor criteria	
1.	Reproduction of spontaneously perceived pain and altered sensations by pressure on trigger point
2.	Elicitation of a local twitch response of muscular fibers by transverse "snapping" palpation or by needle insertion into trigger point
3.	Pain relief obtained by muscle stretching or injection of trigger point

After physical examination, complete blood count, erythrocyte sedimentation rate, C-reactive protein, and liver/renal/thyroid function tests were evaluated.

Patients were excluded if they had concomitant fibromyalgia, pregnancy, cervical nerve root irritation, abnormal laboratory results, thoracic outlet syndrome, or upper extremity entrapment syndromes. Patients who had received a physical therapy program or any local injection therapy within the last 3 months were also excluded from the study.

Subjects who met these entry criteria were then randomized to enter the trial. Subjects were assigned to the study and sham

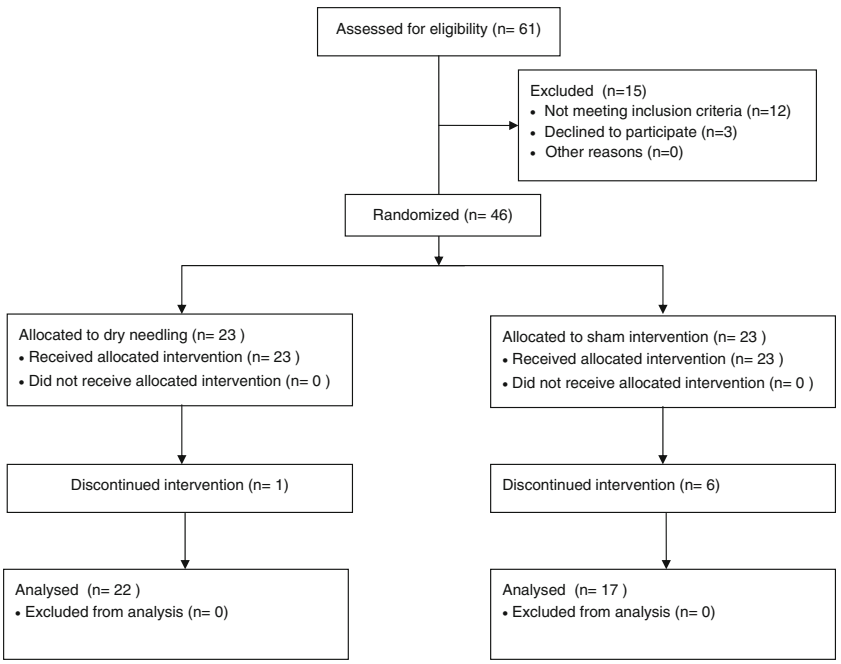

Fig. 1 Consort flowchart diagram

intervention groups by using randomized numbers obtained from QuickCalcs (©GraphPath Software) software.

Group 1 (dry needling)

While the patient was in a sitting position, the trigger point area was determined, and the skin was cleaned with an appropriate antiseptic solution. The trigger point was ensured to be immobilized between the thumb and index finger. Then, the needle was inserted perpendicularly through the skin and moved forward until the trigger point was reached. The needle was withdrawn immediately after pricking.

With the aid of insertion tubes, the standard single-use sterile acupuncture needles (0.25 mm×25 mm) were employed to provide a noxious stimulus (Fig. 2a). In order to minimize the pain of insertion and thus to improve the patients' tolerance of the needling, a certain pressure was applied to the skin with the insertion tube, and then each needle was inserted swiftly to the skin over the trigger points.

Group 2 (sham intervention—placebo—group)

After the trigger points were determined and the skin was cleaned with the same procedures, the blunted needle for sham dry needling which causes a pricking sensation was applied to the trigger points without penetrating the skin after application of a certain pressure to the skin with the insertion tube (Fig. 2b). The same treatment protocol was used for both groups. The treatment protocol was composed of six sessions performed in a period of 4 weeks. The first four sessions were performed twice a week for 2 weeks, and the last two were performed once a week for the last 2 weeks. No exercise program and physical therapy modalities were given during the treatment process. Subjects were asked not to take any nonsteroidal antiinflammatory or muscle relaxant drugs as well. They were only allowed to take paracetamol, and the number of tablets used was recorded. We also queried every subject—concerning the type/amount of medications other than paracetamol—at the evaluation sessions.

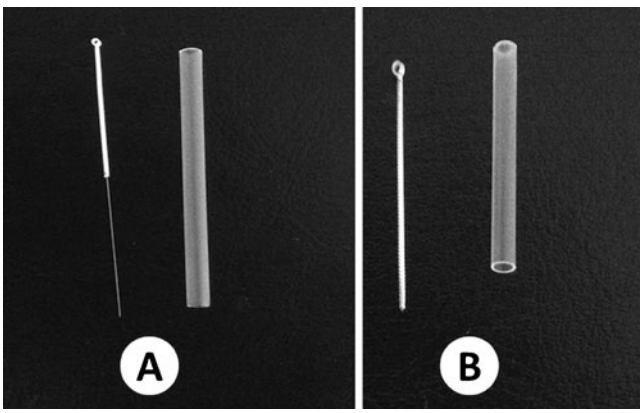

Fig. 2 **a** Standard single-use sterile acupuncture needles. **b** Blunted needle for sham dry needling

Assessment

Pain was evaluated by using a 10-cm visual analog scale (VAS) [12] where the endpoints indicated “no pain” (0) and “worst possible pain” [10]. Quality of Life (QoL) was evaluated by using the Turkish version (validated) of Short Form 36 (SF-36) [13]. Patients were evaluated three times as follows: initially, before the treatment protocol, for VAS and SF-36 (first assessment), after the first treatment session only for VAS (second assessment), and eventually after the sixth treatment session for VAS and SF-36 (third assessment). All injections were performed by the same physician experienced in dry needling (LT), and the evaluations were carried out by another physician who was blinded to the patients' groups. In our study, we did not assess blinding; however, both the patient and the physician who was evaluating the VAS score and SF-36 were blind for the treatment. Moreover, in the dry needling group, the twitch response was also assessed, and the patients were categorized/compared in accordance with its presence or absence.

Statistical analysis

Statistical analysis was done by using SPSS for Windows version 15.0. Since the data were not normally distributed, nonparametric tests were used. Descriptive statistics were expressed as mean±standard deviation. The Mann Whitney *U* test was used for comparisons between the groups, and the Wilcoxon test was used for comparisons within groups. Statistical significance level was set at $p<0.05$.

Sample size calculation was performed by the Power and Sample Size Calculator V. 2.0. We assumed the mean VAS score would be 5 for the sham intervention group and 3 for the patients group, with a common SD of 2. A general linear model (GLM) was performed to analyze the dry needle treatment effect on the last VAS. The baseline VAS score was evaluated as covariate. The sample size was calculated as 17 subjects per group with alpha and beta errors of 5 and 20 %, respectively. The study started with 23 subjects per group considering withdrawals.

Results

Demographic features of the groups are summarized in Table 2. The groups were similar with respect to age, sex, the number of points being treated per session, and trigger

Table 2 Demographic features of the groups

Parameter	Dry needling	Placebo	*p* value
n	22	17	
Sex (female/male)	17/5	14/3	0.843
Age (years)	42.9±10.9	42.0±12.0	0.865
Duration of pain (months)	63.5±50.7	57.9±48.3	0.676

point distribution ($p>0.05$) (Fig. 3). VAS scores were also similar between the groups (Table 3). The GLM results indicate that even after adjusting for baseline VAS score, the last VAS scores still significantly differ by treatment type (F, 36.200; $p<0.001$) (Table 4). As the two groups were similar for common confounders such as age and sex, and composed of similar patients in terms of severity of the pain and trigger points, we did not need to use multivariate analysis (multiple comparison).

In the sham intervention group, VAS scores pertaining to the second and third assessments were found to be significantly decreased when compared with those of the first assessment; however, VAS scores of the second and third assessments were similar (Table 2). In the dry needling group, VAS scores gradually decreased significantly between all assessments (first vs second, first vs third, second vs third) (Table 3). When VAS scores were compared between the groups, although the first assessment scores were similar, the second and third assessment scores were significantly lower in the dry needling group ($p=0.034$ and $p<0.001$, respectively).

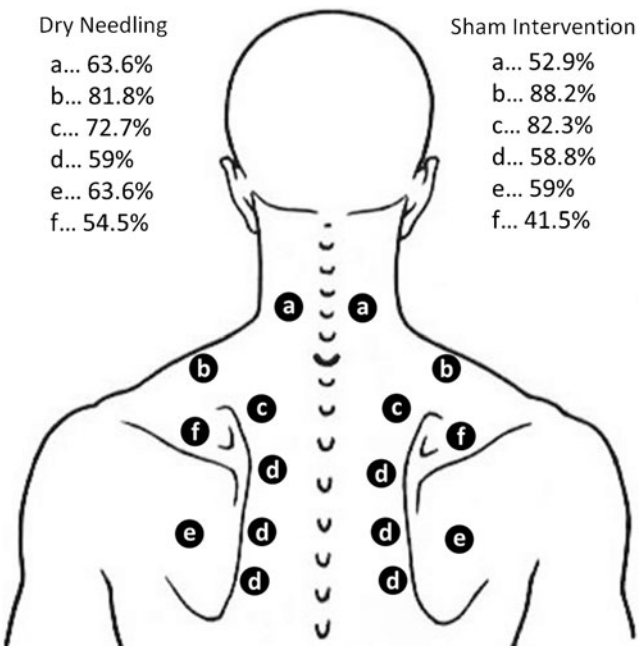

Fig. 3 The groups were similar with respect to age, sex, the number of points being treated per session, and trigger point distribution

Regarding the comparison of SF-36 scores (first vs third assessments), all subgroup values significantly increased in the dry needling group (all $p<0.05$), whereas only those of vitality increased significantly in the sham intervention group (Fig. 4). Concerning the number of paracetamol tablets used (first vs third assessments), while there was no statistical difference in the sham intervention group ($p=0.157$), the number significantly decreased in the dry needling group ($p<0.001$). Hence, while there was no statistically significant difference between the groups before the treatment ($p>0.05$), after the termination of the treatment, the number of used paracetamol tablets was found to be significantly decreased in the dry needling group ($p<0.01$).

When subjects in the dry needling group were further compared according to the presence of a twitch response, duration of pain, VAS, and SF-36 scores were similar at the time of initial assessment. In patients with a positive twitch response, while SF-36 subscores did not change between the first and third assessments ($p>0.05$), VAS scores were found to be decreased between the first vs third assessments (Fig. 5). During the study, any complication related with the treatment procedures was not observed.

Discussion

In this study, we tried to investigate whether the dry needling was really superior to sham intervention in the treatment of MPS. When compared with the sham intervention group, patients who were treated with dry needling showed better improvement with regard to pain and QoL assessment. Although the pain scores have improved in both groups, the findings were significantly better in the dry needling group when compared with the sham group. The patients in the dry needling group also showed a significant improvement for life quality (all subgroups) and medication needs.

The most recent systematic review on the management of MTrPs [14] included seven RCTs in which either acupuncture or dry needling was performed. In one study [15] (whereby MTrP needling was compared with usual care), direct MTrP needling was found to be effective, i.e., a significant short-term reduction in post-stroke shoulder pain was achieved. In two other studies [16, 17] (comparing MTrP needling vs local needling not into MTrP), the results were contradictory, while the former study [16] reported favorable effects of MTrP dry needling and the latter [17] reported similar results with the placebo group. There are also studies which did not report superior effects of dry needling in comparison to nonpenetrating sham interventions [18–21]. Herein, we believe that these contradictory results might be due to the challenges of dry needling studies, the most important of which is perhaps the user dependency of its technique. In our study, we tried to tackle

Table 3 VAS scores of the subjects

Parameter	VAS scores			
	Before treatment	After the 1st session	After the 6th session	*p*
Sham ıntervention (n=17)	6.4±1.6	5.4±1.6	5.3±1.8	$p1$=0.001
				$p2$=0.480
				$p3$=0.017
Dry needling (n=22)	6.6±1.3	4.0±1.6	2.2±2.0	$p1$=0.000
				$p2$=0.000
				$p3$=0.000
p	>0.05		0.000	

$p1$, before treatment vs after the first session; $p2$, after the first session vs after the sixth session; $p3$, before treatment vs after the sixth session

this challenge by letting an experienced physiatrist do all the injections.

Sterling et al. [22] investigated the efficacy of dry needling in patients with chronic whiplash. They have found that combined exercise and dry needling therapy was better that exercises alone. In our study, we only used dry needling to more precisely report on the effects of dry needling. Huguenin et al. [18] studied the effect of dry needling of gluteal muscles in athletes with posterior thigh pain, and they could not find any difference between dry needling and placebo treatments. We attribute their failure to the fact that they used the same needle—as we did in our study—which is not appropriate for the gluteal area whereby a longer needle is needed to bypass the thicker subcutaneous fat layer. Further, their attempt to use multiple insertions might have also caused some sort of local muscle injury and thus pain. In the study by Goddard et al. [23], they have needled either the trigger points or the control points, and they found similar outcomes. In our study, in order to avoid any other noxious (favorable) stimuli, we only used blunt needling.

Dry needling methods were empirically developed to treat musculoskeletal disorders and have been widely used for the treatment of MTrPs after Lewit's publication [8]. He emphasized that the effect of injections was primarily caused by the mechanical stimulation of an MTrP with the needle. In this approach, the needle is inserted directly into an MTrP, and thin needles are usually preferred in order to provide maximum analgesic effect by pricking them into the most painful points [1, 24]. Similarly, in our study, we used acupuncture needles for the treatment of MTrPs in the dry needling group (Fig. 2b). On the other hand, in the placebo group—as described in previous studies [25, 26]—a blunted needle for sham dry needling was applied without penetrating the skin by using an insertion tube (Fig. 2b). In order to avoid two-point discrimination and to provide patient blinding, we applied a certain pressure to the skin with the insertion tube which has a diameter of approximately 2 mm. Normally, a person can recognize two points separated by as small as 30–40 mm on the back. In this way, we also improved the patients' tolerance and compliance to the needling therapy.

Blunt needles may cause some sort of stimulus as well which is not as much as the acupuncture needles. Accordingly, we attribute the decrease in VAS scores in the sham intervention group to this transient (and relatively weak) effect, and we further believe that the lack of persistent changes in VAS scores towards the sixth treatment supports our hypothesis. On the other hand, we have observed ongoing decrease in VAS scores in the dry needling group possibly due to efficient stimuli in each session. Overall, concordantly to the relevant literature [6, 7], our results have shown that MTrP needling is effective in reducing pain. Moreover, similar to Ceccherelli et al. [27], our results imply that muscle afferents could be more important than skin afferents also for the transmission of analgesic signals. Likewise, Itoh et al. [17] proposed the presence of polymodal-type receptors (nearby MTrPs) that are responsive to mechanical, thermal, and chemical stimuli [28]. In this regard, needle stimulation of such receptors in the muscle may produce stronger effects on pain relief. On the other hand, these receptors may be present in the skin, and they may also be responsible for the analgesic effects after stimulation of the skin by blunt needles. Similar to the VAS scores, improvement in SF-36 scores was much more significant in the dry needling group. While all subgroups improved in the dry needling group, only the vitality subgroup improved in the sham intervention group. Further, the changes in the VAS and SF-36 scores were significantly reflected in the

Table 4 Evaluation of the effect of treatment groups on the last VAS score by GLM

Source	Type III sum of squares	*df*	Mean square	*F*	Sig.
Baseline VAS	48.529	1	48.529	19.373	0.000
Groups	90.678	1	90.678	36.200	0.000

R^2=0.608

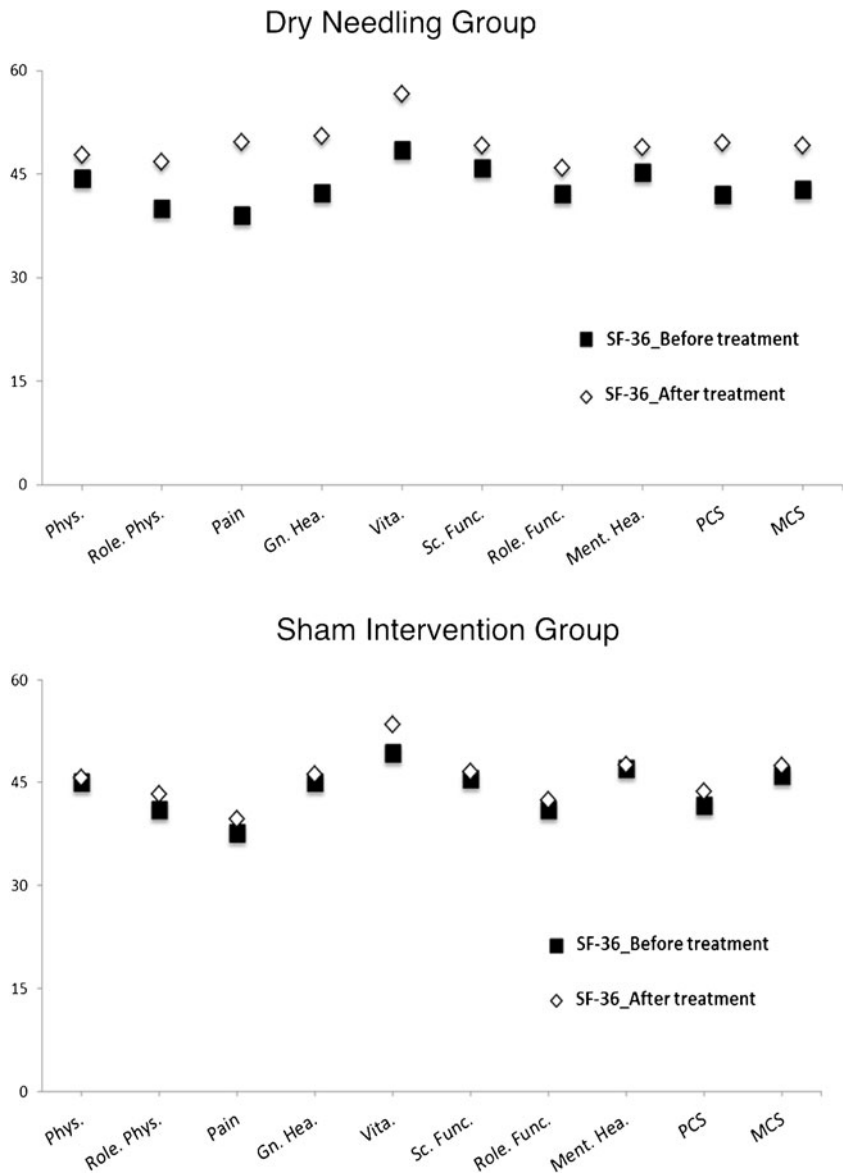

Fig. 4 All subgroup values significantly increased in the dry needling group (all $p < 0.05$), whereas only those of vitality increased significantly in the sham intervention group

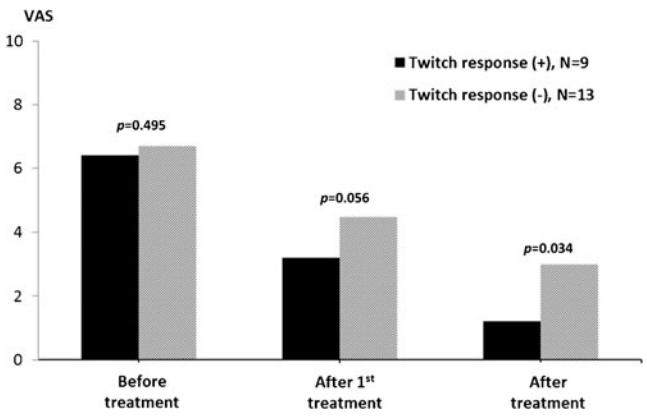

Fig. 5 VAS scores were found to be decreased between the first vs third assessments

paracetamol use of the patients (decreased in the dry needling group but not in the sham intervention group).

Local twitch response is defined as an involuntary, localized, and temporary contraction in one part of the taut band during trigger point needling [29]. Some authors have suggested that trigger point needling is more likely to be effective if it produces a local twitch response [9, 30]. Our results support this hypothesis, as we found better improvement in pain scores of patients with local twitch response in comparison to those without.

Limitations

The most important drawback of this study is the limited number of subjects and the lack of long-term follow-up. Additionally, in order to have better access to the trigger

points of several subjects with varying muscle morphology, different needles could have been used.

As summary, we may conclude that dry needling performed on MTrPs seems to be more effective than sham needling both with respect to pain management and QoL in the treatment of MPS. Further studies with larger samples are definitely awaited especially to clarify the relevant physiological mechanisms of this treatment method.

Disclosures None.

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