Efficacy of trigger points self-massage in chronic tension-type headache: An unmasked, randomized, non-inferiority trial

Narges Karimi, Mohammad Tabarestani, Athena Sharifi-Razavi

Abstract

Background & Objectives: Chronic tension-type headache (CTTH) is a disabling disorder that can cause considerable pain and negative impact on the individual’s health. We compared the efficacy of trigger point self-massage to standard drug treatment in patients with CTTH.

Methods: This was a randomized study with an active comparator on CTTH patients. Eighty participants were randomized to an intervention or comparator group. Participants in the comparator group received tablet nortriptyline 10 mg daily and the participants in the intervention group were treated with trigger point self-massage at 8 different points 3 times a day for 4 weeks. The intensity, frequency and duration of headaches as well as the number of analgesic pills consumed; were recorded in a diary at week 1 and week 4 of intervention. A 30% decrease in headache index was taken as the minimum clinically important difference as per IHS guidelines.

Results: The headache index decreased from 92.53±50.98 to 37.73±27.13 in the nortriptyline group and from 81.60±33.97 to 45.32±24.75 in the massage group (p=0.04, f:4.31). Headache intensity by the Visual Analogue Scale decreased from 5.37±1.66 to 3.37±1.44 in the nortriptyline group and from 5.00±1.98 to 3.81±1.31 in the massage group (p=0.03, f:4.5). Headache duration reduced from 16.88±11.43 to 10.12±11.43 hours in the nortriptyline group and from 15.83±5.83 to 11.87±5.50 hours in the massage group (p=0.04, f:4.07). Headache frequency decreased from 3.42±1.15 to 2.22±0.91 per week in the nortriptyline group and from 3.55±1.03 to 2.62±1.59 to 0.67±0.72 in the massage group (p=0.02, f:5.25).

Conclusion: Trigger point massage is an effective and safe strategy for prophylactic treatment of CTTH, but is inferior to nortriptyline in terms of efficacy.

Keywords: Chronic tension-type headache, manual massage, therapy, trigger points.

INTRODUCTION

Chronic tension-type headache (CTTH) is a disabling disorder which can cause considerable pain and negative impact on the individual’s health. The exact pathogenesis of CTTH is not understood. Both peripheral and central mechanisms have been suggested, nevertheless, central sensitization through the presence of persistent nociceptive stimulus from active myofascial trigger points (TP) is one of the most accepted theories. A TP is described as a tender spot located at a tense band of muscle fibers or fascia. TPs may be latent or active, and when manipulated become excited and can produce referred pain, motor dysfunction and autonomic phenomena. Local biochemical changes, including increased availability of pro-inflammatory substances such as substance P, IL-1β and tumor necrosis factor (TNF)-α—activate muscle nociceptors, potentially contributing to peripheral mechanisms by sensitizing nociceptive nerve endings. It is noted that prolonged nociceptive inputs from TPs can induce plastic changes in the brain, resulting in development and maintenance of chronic musculoskeletal pain. A brief nociceptive stimulation can activate endogenous pain inhibitory mechanisms and restrain nociceptive processing. These findings suggest that analgesic effects of TP compression may be expected through effects on the central nervous system.
Since peripheral and central sensitization is commonly maintained by persistent peripheral nociceptive input, active and latent TP should be viewed as potential sources of such an input and addressed in treatment of CTTH.9

TPs in patients with CTTH are almost always present in upper trapezius, suboccipital, masseter, sternocleidomastoid, temporalis, superior oblique, ocular, frontalis and splenius capitis muscles.1 Many conventional therapies have been tried in the treatment of TPs, including: local anesthetic injection, thermotherapy, cupping, massage, ischemic compression, dry needling and neural mobilization techniques.4,5,10,11 Compression at TPs can increase the lactate concentration and cause a significant increase in the pressure pain threshold9,12, and is an effective massage technique for acute musculoskeletal pain.8

Pharmacological treatments are considered the main interventions even though elevated frequency of attacks increases the risk of drug abuse.13 Amitriptyline and nortriptyline 10-100 mg/day are first-line prophylactic drugs for CCTH in most guidelines.14 However, compliance with prophylactic drugs is often poor, and their efficacy may be restricted because of this.15 For this reason, non-pharmacological management should always be considered in CTTH.15 The European Federation of Neurological Societies guidelines states that the use of non-pharmacologic therapies has fewer side effects than pharmacological therapies.16 In fact, manual therapies are the therapeutic strategy most requested by patients with tension type headache.17 While many techniques exist that can impact TPs, self-massage therapy is particularly interesting due to its availability, relatively low cost, patient interest, informality and treatment effectiveness.6 The present study aimed to determine if massage therapy with self-compression technique is as effective as nortriptyline for CTTH prophylaxis.

METHODS

This study was a prospective, randomized, parallel, active comparator, unmasked trial with a 1:1 allocation ratio. The participants were recruited from one outpatient site (Tooba clinic) the university clinic of Mazandaran University of Medical Sciences, in Sari, Iran, during February 2016 - March 2019. The duration of study was 4 weeks.

The participants were patients who were 18 to 60 years old with full criteria of CTTH according to ICHD-318 (Table 1). They were included if painful trigger points around the head were found on physical examination, had no contraindication for massage, did not under prophylactic treatment at least one month before enrollment and had provided written informed consent.

The exclusion criteria were: dementia or severe cognitive impairment, treatment with other complementary methods or drugs with potential prophylactic effect on CTTH in the past one month, history of rheumatoid arthritis or cervicocephalic fracture or other skeletal deformity.

A total of 80 participants were randomized to 2 groups in a 1:1 ratio. Random sample selection was based on block balance randomization with 4 blocks. The intervention and control groups were named A and B, so that from the four blocks that will be shown in 6 states (AABB, BBAA, ABAB, BABA, ABBA, BAAB) and using the table of random numbers, the row of blocks will be selected.

The total study duration was 4 weeks. In each treatment protocol 2 clinic visits (at the beginning of the first week) and end of the

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**Table 1: ICHD-3 Criteria of chronic tension-type headache**

<table>
<thead>
<tr>
<th>A.</th>
<th>Headache occurring on &gt;15 days/month on average for &gt;3 months &gt;180 days/year), fulfilling criteria B-D</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.</td>
<td>Lasting hours to days, or unremitting</td>
</tr>
<tr>
<td>C.</td>
<td>At least two of the following four characteristics:</td>
</tr>
<tr>
<td>1.</td>
<td>bilateral location</td>
</tr>
<tr>
<td>2.</td>
<td>pressing or tightening (non-pulsating) quality</td>
</tr>
<tr>
<td>3.</td>
<td>mild or moderate intensity</td>
</tr>
<tr>
<td>4.</td>
<td>not aggravated by routine physical activity such as walking or climbing stairs</td>
</tr>
<tr>
<td>D.</td>
<td>Both of the following:</td>
</tr>
<tr>
<td>1.</td>
<td>Neither moderate or severe nausea nor vomiting</td>
</tr>
<tr>
<td>2.</td>
<td>no more than one of photophobia or phonophobia or mild nausea</td>
</tr>
<tr>
<td>E.</td>
<td>Not better accounted for by another ICHD-3 diagnosis.</td>
</tr>
</tbody>
</table>
fourth week) and 1 telephone contact (during the second week) was made. The first visit evaluation included history taking and neurological examination by the neurologist. Neuroimaging was performed according to the discretion of the attending physician prior to enrollment in the study. The second visit included a review of the headache diary over the 4th week and a brief evaluation. At the end of week 2 their adherence to treatment was checked by telephone contact.

**Intervention**

Participants in the comparator group were treated with a standard drug for CTTH prophylaxis, nortriptyline 10 mg tablets daily at bedtime for 4 weeks. The intervention group received massage of trigger points at 8 different points 3 times a day for 4 weeks. The points of compression were at the masseter, sternocleidomastoid, frontalis and splenius capitis muscles as shown in Figure 1.

A medical student instructed subjects on the massaging method and explained how to record the headache diary. The patient was placed in a comfortable chair in a relaxed position. The points were identified and shown to the patient. Then the index finger was pressed directly onto each point to produce pain that was just acceptable to the patient. Massage was then performed in approximately 1 cm circular movements for 1 minute. Thereafter, the patient repeated the procedure to ensure that the treatment was correctly performed. The patient was then requested to perform the procedure 3 times a day for 4 weeks. Written informed consent was obtained from patients before starting any intervention.

**Measures and outcomes**

Participants recorded time of start and stop of each headache episode and its intensity in a diary during week 1 and week 4. Also, the number and the type of analgesic pills used were recorded. The total headache duration for a given day was calculated by summing up the duration of all headache episodes occurring that day.

Figure 1. Point of massage in frontalis (A), masseter (B), splenius capitis (C) and sternocleidomastoid (D) muscles.
The baseline headache status was determined from headache diary records in the first week, and response to treatment was determined from headache diary records in the fourth week. We measured the average of headache intensity and duration for weeks 1 and 4 and used this for data analysis.

The intensity of headaches was assessed by a visual analogue scale score (VAS) 11-point numerical scale (0–10, in which 0 indicates no headache, 5 indicates moderate headache and 10 indicates the worst headache imaginable). Participants were asked to record the average pain intensity of their headache episodes.

A minimally clinical important difference was considered to be a 30% decrease in headache variables, according to IHS guidelines. The primary outcome was the headache index change in week 4 from the baseline (week 1). Secondary outcomes were change in headache intensity, frequency, duration and number of analgesics consumed. Headache index or area-under-the-headache-curve (AUC) of one week was calculated as follows: Duration of headache (hours) \times headache intensity (VAS) for each day, added up from day 1 to day 7 of a given week (Figure 2). Headache intensity, frequency, duration as well as analgesic drug consumption were defined as mean intensity of headaches in one week, mean number of attacks occurring in one week, mean duration of headaches in one week and the mean number of analgesic pills used in one week.

The study protocol was approved by the ethical board of the Mazandaran University of Medical Sciences, Sari, Iran (code: 13/12/1393) and was registered in ClinicalTrials.gov (NCT04232046).

**Statistical analysis**

The number of subjects in each group was determined based on previous clinical trial data. We calculated that at least 35 participants in each group were required to detect a 30% difference in headache intensity with a significance level of 0.05 and power of 80%. With a calculated loss of 10% of participants in the trial, we enrolled 80 patients.

For statistical analysis of the data, SPSS 20 was used. Intention-to-treat analysis was used to analyze the main outcome. Data were expressed as means, standard deviations and 95% confidence intervals. Analysis of co-variance (ANCOVA) was used to assess the group differences of mean change for each treatment group. The level of significance was set as \( P < 0.05 \) for all analyses.

The responder rate was presented as number needed to treat (NNT) and also risk ratio (RR) with a CI of 95%. We also evaluated the effect size based on “variance explained” Cohen’s \( d \) was interpreted as no effect (\( d=0-0.2 \)) small effect (\( d=0.2-0.5 \)) intermediate effect (\( d=0.5-0.7 \)) and large effect (\( d=0.8-1.0 \)).

**RESULTS**

The assessment for eligibility was done on 260 patients (age 18-60) with the chief complaint of a chronic headache. One hundred and sixty eight of them met the criteria of CTTH; 125 met all inclusion criteria. After considering exclusion criteria, 80 participants were enrolled (40 participants in each group) from February 2016 to March 2019. The most common exclusion criteria was the use of drugs with potential prophylactic effects on CTTH. There was no loss to follow up in both groups (Figure 3).

Of the 80 participants, 16 (20%) were male and 64 (80%) were female. The mean age of participants was 32.04±8.23 years (range 19-56). Demographics and baseline characteristics (Table 2) were normally distributed in the two groups.

All variables of headache were significantly improved in both groups (\( p<0.001 \)) (Table 3). To overcome a high placebo effect in patients with CTTH, we regarded a 30% or greater reduction in headache parameters as sufficient taken to represent a good response in our trial.

The headache index reduced from 92.53±50.98 to 37.73±27.13 in the nortriptyline group and from 81.60±33.97 to 45.32±24.75 in the massage group. (\( p<0.001 \), \( p<0.001 \)). Thirty-four (85%) patients in the nortriptyline group and 24 (60%) in the massage group reached a 30% reduction in the

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**Figure 2. Headache index calculation formula**

\[
\text{Headache Index} = (D_1 \times I_1) + (D_2 \times I_2) + (D_3 \times I_3) + (D_4 \times I_4) + (D_5 \times I_5) + (D_6 \times I_6) + (D_7 \times I_7)
\]

\( D: \) duration of headache (H)  
\( I: \) intensity of headache (VAS)  
\( 1: \) Day 1 through Day 7
Figure 3. Participant enrollment flow diagram
Table 2: Baseline characteristics of participants

<table>
<thead>
<tr>
<th></th>
<th>Medication N=40</th>
<th>Self-massage N=40</th>
<th>P</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex: Male</td>
<td>8(20%)</td>
<td>8(20%)</td>
<td>0.98</td>
<td>-3.66,3.71</td>
</tr>
<tr>
<td>Age</td>
<td>32.02±8.12</td>
<td>32.05±8.44</td>
<td>0.26</td>
<td>-8.40,30.16</td>
</tr>
<tr>
<td>Headache variables</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Index</td>
<td>92.53±50.98</td>
<td>81.60±33.97</td>
<td>0.26</td>
<td>-8.40,30.16</td>
</tr>
<tr>
<td>Intensity</td>
<td>5.37±1.66</td>
<td>5.00±1.98</td>
<td>0.37</td>
<td>-0.45,1.17</td>
</tr>
<tr>
<td>Duration</td>
<td>16.88±11.43</td>
<td>15.83±5.83</td>
<td>0.60</td>
<td>-2.99,5.09</td>
</tr>
<tr>
<td>Frequency</td>
<td>3.42±1.15</td>
<td>3.55±1.03</td>
<td>0.62</td>
<td>-0.63,0.38</td>
</tr>
<tr>
<td>Analgesic</td>
<td>2.85±1.49</td>
<td>2.62±1.59</td>
<td>0.22</td>
<td>-0.46,0.91</td>
</tr>
</tbody>
</table>

Table 3: Variable changes from week 1 to week 4

<table>
<thead>
<tr>
<th></th>
<th>Index</th>
<th>Intensity</th>
<th>Duration</th>
<th>Frequency</th>
<th>Analgesic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 1</td>
<td>92.53±50.98</td>
<td>5.37±1.66</td>
<td>16.88±11.43</td>
<td>3.42±1.15</td>
<td>2.85±1.49</td>
</tr>
<tr>
<td>Week 4</td>
<td>37.73±27.13</td>
<td>3.37±1.44</td>
<td>10.12±11.43</td>
<td>2.12±1.15</td>
<td>1.22±1.27</td>
</tr>
<tr>
<td>Intergroup P</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Self-massage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 1</td>
<td>81.60±33.97</td>
<td>5.00±1.98</td>
<td>15.83±5.83</td>
<td>3.55±1.03</td>
<td>2.62±1.59</td>
</tr>
<tr>
<td>Week 4</td>
<td>45.32±24.75</td>
<td>3.81±1.31</td>
<td>11.87±5.50</td>
<td>2.22±0.91</td>
<td>0.67±0.72</td>
</tr>
<tr>
<td>Intergroup P</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Between groups P</td>
<td>0.041</td>
<td>0.037</td>
<td>0.047</td>
<td>0.908</td>
<td>0.025</td>
</tr>
<tr>
<td>(ANCOVA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>4.31</td>
<td>4.5</td>
<td>4.07</td>
<td>0.01</td>
<td>5.25</td>
</tr>
</tbody>
</table>

Table 4: Responder rates: achieving good outcome

<table>
<thead>
<tr>
<th>Value</th>
<th>Medication n=40</th>
<th>Self-massage n=40</th>
<th>RR 95% CI</th>
<th>HR</th>
<th>RD</th>
<th>p</th>
<th>NNT</th>
<th>d_ohen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index</td>
<td>34(85)</td>
<td>24(60)</td>
<td>0.70</td>
<td>-25%</td>
<td>-0.25</td>
<td>0.01</td>
<td>-4</td>
<td>-0.51</td>
</tr>
<tr>
<td>Intensity</td>
<td>28(70)</td>
<td>18(45)</td>
<td>0.64</td>
<td>-25%</td>
<td>-0.25</td>
<td>0.02</td>
<td>-4</td>
<td>-0.46</td>
</tr>
<tr>
<td>Duration</td>
<td>27(67.5)</td>
<td>19(47.5)</td>
<td>0.70</td>
<td>-20%</td>
<td>-0.20</td>
<td>0.07</td>
<td>-3</td>
<td>-0.37</td>
</tr>
<tr>
<td>Frequency</td>
<td>24(60)</td>
<td>23(57.5)</td>
<td>0.95</td>
<td>-2%</td>
<td>-0.02</td>
<td>0.82</td>
<td>-40</td>
<td>-0.05</td>
</tr>
<tr>
<td>Analgesic</td>
<td>25(62.5)</td>
<td>36(90)</td>
<td>1.44</td>
<td>27%</td>
<td>0.27</td>
<td>0.006</td>
<td>4</td>
<td>0.82</td>
</tr>
</tbody>
</table>
headache index. Trigger point massage decreased headache index 25% less than with nortriptyline (60% vs 85%) (RR = 0.70 with 95%CI = 0.53-0.93; NNT =-4, p=0.01, dcohen = 0.51). 95% CI did not cover value of 0 (Table 4).

Although TP massage was effective in reducing headache intensity, duration and frequency, it was significantly less effective than nortriptyline, with a small differential effect (dcohen=0.46, 0.37, 0.05).

TP massage decreased headache intensity 25% less than with nortriptyline (45% vs 70%) (RR =0.64 with 95%CI = 0.43-0.95 ; NNT =-4 , p=0.02, dcohen = 0.46]. TP massage decreased headache duration 20% lower than nortriptyline (47.5% vs 67.5%) group (RR =0.70 with 95%CI = 0.47-1.03 ; NNT =-3 , p=0.07, dcohen = 0.37]. TP massage decreased headache frequency 2% less than with nortriptyline (57.5% vs 60%) (RR =0.95 with 95%CI = 0.66-1.38 ; NNT =-40 , p=0.82, dcohen = -0.05]. Interestingly, the number of analgesic pills in the massage group were considerably fewer than in the nortriptyline group, with a large differential size effect (dcohen=0.82). TP massage decreased the amount of analgesic consumption 27% more than nortriptyline (90% vs 62.5%) (RR =1.44 with 95%CI = 1.10-1.87; NNT =4, p=0.006, dcohen =0.82).

The analgesic drugs used in order of frequency were Novafen (acetaminophen/caffeine/ibuprofen), ibuprofen, acetaminophencodein, diclofenac and celecoxib. There were no adverse effects in the massage group. Three cases in the nortriptyline group complained about mouth dryness, and 2 cases complained of somnolence.

DISCUSSIONS

The present study showed that both nortriptyline and TP massage improve all variables of headache in patients with CTTH. In terms of headache index, intensity and duration, TP self-massage was significantly less effective than nortriptyline, with a small differential size effect. The efficacy of self-massage was not different from nortriptyline in reducing headache frequency. Analgesic drug consumption in the massage group was markedly reduced in comparison to the nortriptyline group.

Only a few studies of non-pharmacological interventions addressing CTTH were found on a literature search. A recent systematic review suggested that further research with a stronger methodological design is required because of insufficient evidence.13 Quinn et al. reported significant reduction of headache frequency within the first week of massage therapy for CTTH (p=0.009) but there was no effect on headache intensity (p=0.19). The result of this study is inconclusive because of an extremely small sample size (n=4) without a control group. Moraska et al. in a randomized, placebo-controlled trial showed headache frequency decreased from the baseline for both TPs massage (p=0.0003) and placebo (p=0.013), with no difference between massage and placebo. Intensity, duration and drug consumption did not change significantly. This suggests that CTTH, like other chronic conditions, is responsive to placebo. Berggreen et al. compared TP massage with no treatment in a randomized trial and reported significant improvement in morning pain in the treatment group compared with the control group (95% CI 0.11–17.4), p = 0.047). Reduction in analgesic consumption occurred but was not significant. Shields et al. in a case series, reported headache frequency reduction after myofascial TPs release in 4 patients suffering from CTTH, but without any effect on headache duration and intensity.1 Altogether, in most studies the frequency of headaches is the most responsive variable to TP massage therapy. Given that various factors may affect the CTTH variables1-23, headache frequency alone is not a good indicator of CCTH disability; rather, intensity and duration are more significant. For this reason, these individual measures of change are less useful than a headache index incorporating an area-under-the-headache-curve parameter.15 In our literature review we did not find any study to measure this variable for TP massage in CTTH. In our study the headache index showed the highest change as compared to headache duration, frequency and intensity. Gilder et al. in a double-blind randomized study also employed a headache index to show that insertion of a dry needle into active TPs resulted in a significant decline in mean headache index and intensity scores in comparison to sham therapy; where needles were inserted into incorrect points.19 This study also supports the rationale for addressing TPs in CTTH therapy.

Equalization of the length of the muscle sarcomeres, reactive hyperemia in the TPs, spinal reflexes, mobilization and stretching of the TP taut band, and temporary elongation of the connective tissue, have been proposed as explanations of the therapeutic effects of massage therapy.24 In the present study massage was not applied to all of an individual patient’s active TPs, but covered fixed points. This may account for a lower therapeutic response in the massage group.
When the duration of CTTH increases, central sensitization may increase correspondingly, so treatment to normalize this central sensitization should be repeated as often as necessary to decrease the symptoms of the patient. It should be noted that selecting an easy, tolerable and pragmatic treatment to control the headache attacks with acceptable adherence is necessary. Most physical therapy strategies need professional therapists and involve a high degree of time and cost. By contrast, self-massage of TPs is an accessible, effective and low-cost method.

In present study the number of analgesic pills in the massage group were considerably fewer than in the nortriptyline group. The nortriptyline effect usually sets in after 2-4 weeks, but TPs massage seems to work immediately. In a meta-analysis the effectiveness of tricyclic antidepressants on headaches was evaluated and the results showed that patients taking tricyclics for tension-type headaches used fewer analgesics. Moreover, the effect seems to increase over time; patients in the first month of treatment had less improvement. For this reason, if the duration of our study was longer, the effect of nortriptyline may be more prominent. Nonetheless, by considering NNT=4 to reduce the symptoms of the patient, it should be noted that selecting an easy, tolerable and pragmatic treatment to control the headache attacks with acceptable adherence is necessary. Most physical therapy strategies need professional therapists and involve a high degree of time and cost. By contrast, self-massage of TPs is an accessible, effective and low-cost method.

CTTH patients with poor adherence to prophylactic drug treatment; patients with multi drug treatment and patients who are vulnerable to drug side effects, may also benefit from TP massage.

Finally, our study confirms that massage therapy is an appropriate intervention for CTTH patients. The main limitations of our study were the short duration of treatment, and the lack of supervision of massage technique in our patients. Also, we did not treat all problematic muscles contributing to CTTH in each individual. Our patients were mainly women (80%), which may affect generalization of results to all CTTH patients. But, CTTH is more common in women, and this study sample may refer to the most representative population suffering from CTTH.

In conclusion, TP self-compression massage is an effective, safe, available, informative and cost-effective strategy for prophylactic treatment of CTTH, but it is inferior in comparison to nortriptyline.

ACKNOWLEDGEMENT

We would like to appreciate the Vice Chancellor of Research and Technology of MAZUMS for ethical approval and financial support of this trial. This study was Mohammad Tabarestani’s doctoral dissertation towards graduation in general medicine. We also thank Amir Ali Rezaei for his consent to publish his photo in Figure 1.

DISCLOSURE

Conflict of Interest: None

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