The Effect of Foot Massage on Pain Intensity and Anxiety in Patients Having Undergone a Tibial Shaft Fracture Surgery: A Randomized Clinical Trial

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Objective: To determine the effect of massage therapy on pain intensity and anxiety in patients who have undergone tibial shaft fracture surgery.

Design: This study was a randomized clinical trial with a pre–post design. As the study included 2 treatment groups, it was a parallel study.

Setting: Khatam-Al-Anbia Hospital in Zahedan, Iran, between July and August 2017.

Patients: In all, 66 patients who underwent a tibial shaft fracture surgery were enrolled and randomly assigned to intervention and control groups (33 patients each).

Intervention: The intervention included a 10-minute foot massage (5 minutes per leg) using sweet almond oil, the most common lubricant used in massage therapy.

Main Outcome Measurements: Data were collected using pain numeric rating scale and Spielberger State-Trait Anxiety Inventory before and after intervention.

Results: After intervention, the mean scores for pain intensity, and anxiety in the intervention and control groups were 4.72 (0.97) and 5.72 (0.91), and 42.84 (6.50) and 58.36 (10.37), respectively. A significant difference was noted between the intervention and control groups concerning pain intensity and anxiety.

Conclusions: The results indicated that massage therapy reduced pain intensity and anxiety in patients who underwent tibial shaft fracture surgery. Therefore, using massage as a noninvasive and acceptable intervention is suggested in orthopaedic surgery, especially after tibial shaft fracture surgeries.

Key Words: anxiety, complementary therapies, massage, pain, postoperative

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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INTRODUCTION

The first and most frequent complication in adult tibial shaft fractures is pain. Other complications noted in orthopaedic patients are psychological distress and mental health impairments. Anxiety as the most common emotional factor predicted postoperative pain. Furthermore, one-third and half of postoperative orthopedic surgery patients have been reported to be anxious and depressed, respectively. Anxiety and depression in arthroscopic subacromial decompression worsen surgical outcomes, for example, by causing an increase in pain.

One effective strategy for pain management and adherence improvement may be complementary and alternative intervention. One of the effective and acceptable complementary and alternative interventions is massage therapy. Massage therapy relaxes osteoarthritis patients and improves their quality of life. Moreover, massage as a relaxation technique might improve quality of sleep. A literature review on the effect of massage therapy on surgery patients has shown that it reduces pain intensity in patients after appendectomy and thoracic surgery. Moreover, surgery patients who receive massage therapy have reported less anxiety, depression, fatigue, confusion, and anger.

A literature review on the effect of massage therapy after orthopaedic surgery showed a limited number of studies conducted on the topic. It was indicated that using massage intervention in male patients who had undergone arthroscopic knee surgery reduced pain intensity. However, it could not relieve pain completely. Another study reported that massage increased the patellofemoral function and range of motion in the knee and reduced pain in patients after anterior cruciate ligament reconstruction. In contrast, Miller et al...
reported that there was no difference between the 2 groups of postoperative orthopaedic patients who received analgesic treatment alone and analgesic and massage treatments for pain and anxiety. However, only few studies have been conducted on the effect of massage on pain relief in orthopaedic surgeries. Moreover, there is a controversy about the effect of massage on pain relief and reduction of anxiety in patients after surgery. In addition, no study has been conducted on the effect of massage after a tibial shaft fracture surgery. Therefore, we aimed to determine the effect of foot massage on the pain intensity and anxiety in patients who underwent a tibial shaft fracture surgery.

**PATIENTS AND METHODS**

This was a randomized clinical trial with a pre–post design. The study was conducted in 2 groups (intervention and control); therefore, it was a parallel study.

The study was conducted at Khatam-Al-Anbia Hospital, Zahedan, Iran, from July to August 2017.

The target population was patients who had undergone tibial shaft fracture (shinbone) surgery. The inclusion criteria for subjects were age of ≥18 years, an open reduction and internal fixation surgery for a tibial fracture, hospital admission for at least 1 day after surgery in orthopaedic surgery wards, and orientation of time, person, and place. Subjects with decreased consciousness (whose ability to remain awake, aware, and oriented was impaired), a history of diabetes for more than 10 years, and neurological, cerebrovascular, psychiatric, and respiratory diseases were excluded.

The patients were randomly assigned to the intervention or control group using block randomization, which was conducted by a research assistant who was not participating in the trial. In this study, the research assistant who collected the data and the statistician who analyzed the data were blind to the study groups.

Based on a previous study on pain with an effect size of 0.63, a pain standard division of 0.84, $\alpha = 0.05$, and $\beta = 90\%$, the sample size was estimated to be 29 subjects in each group. Furthermore, based on a power of 90%, $\alpha = 0.05$, and an effect size of $-0.95$ for anxiety, the sample size was determined to be 24 subjects in each group. Therefore, a sample size of 66 subjects (33 in each group) was estimated for our study, keeping in mind the largest sample size from the above studies, which corresponded to that of the study on pain, and a dropout rate of 12%.

At the beginning of the study, 83 patients were found to be eligible for assessment. However, 7 subjects did meet the inclusion criteria, 2 withdrew, and 8 refused to participate. Therefore, 66 patients were included in the study and were randomly enrolled in the intervention and control groups. There were no study drop-outs during the follow-up period between the second and third days after the surgery and analysis (Fig. 1).

**FIGURE 1.** Flow chart of patients with an operatively treated tibial shaft fracture who participated in this study.
Before the massage, the patients were asked to be in a comfortable and unconstrained position in the bed and were helped to be in supine position. The intervention was performed as a foot massage (the feet, legs, heels, and toes were included) from the heel to the fingertips for 5 minutes for each leg (total time: 10 minutes) using sweet almond oil, the most common lubricant used in massage therapy. During the massage, the subjects’ foot was elevated using a pillow. The massage procedure was performed on both sides of the foot (plantar and dorsal sides), such that the fingers were placed on the dorsal side of the foot and the thumbs on the plantar side. Then, the plantar region of the foot was pressed with one thumb, stroking upward using less pressure. This was done first on the heel and was later continued on the toes, holding the plantar side of the foot facing the therapist so that the fingers of the therapist are placed on the dorsal side of the toe. This procedure was repeated 5–10 times. Caution should be exercised for avoiding massaging the areas affected by burns, bruising, inflammation, thrombosis, jaundice, redness, swelling, and pain, and areas that feel warm.

Massages may result in complications such as disc herniation, dissection of the vertebral arteries, soft tissue trauma, neurologic compromise, and spinal cord injuries. Therefore, the trial should be stopped if any complications related to the massage occur. However, no serious or considerable complications or adverse events were reported.

The intervention group received a foot massage on the second day after the surgery (approximately 20 hours after the surgery) with the doctor’s permission. They also received routine care. The control group received routine care in the same manner as the intervention group.

This study was approved by the Ethics Committee of Shiraz University of Medical Sciences (Code number: 95-01-08-13625). All the patients signed an informed consent form. In this form, the study’s aim and the intervention were explained. Participation in this study was voluntary, and the patients were informed that their information would be published in general.

SPSS version 21 was used to analyze the data. Chi-square test was used for compare demographic characteristics. Moreover, as Kolmogorov–Smirnov test showed that all the variables including pain intensity and anxiety are not normally distributed, non-parametric tests such as Mann–Whitney U test and Wilcoxon rank sum test were used for data analysis. Moreover, Friedman test was used to compare

| TABLE 1. Demographic Characteristics of the Intervention and Control Groups |
|------------------|------------------|------------------|------------------|
| Variables        | Intervention n (%) | Control n (%) | P     |
| Gender           | Male             | Female          |       |
|                  | 26 (79)          | 7 (21)          | 0.80  |
| Age group (y)    | 20–29            | 30–39           | 40–50 | 0.47  |
|                  | 7 (21)           | 26 (79)         | 0.00  |
|                  | 13 (39)          | 17 (51)         |       |
|                  | 3 (9)            |                 |       |
| Marital status   | Married          | Single          | 0.57  |
|                  | 25 (76)          | 8 (24)          |       |
|                  | 24 (73)          | 9 (27)          |       |
| Educational levels | University | Diploma | School | 0.70  |
|                  | 0 (0.0)          | 8 (24)          | 25 (76) |       |
|                  | 1 (3)            | 8 (24)          | 24 (73) |       |

School refers to high school, secondary school, or primary school.

The outcome measures of this study were pain intensity and anxiety. All these parameters were first assessed before the intervention (the second morning after the surgery). After intervention, the pain intensity was measured after 0.5 and 2 hours, and the anxiety score was determined immediately.

A demographic form, pain numeric rating scale (NRS), and Spielberger State-Trait Anxiety Inventory (STAI) were used for data collection.

NRS is a common rating scale for determining pain intensity. The scale is a horizontal ruler that is 100 mm long and is numbered from 0 to 10. The number 0 suggests “no pain” and number 10 indicates “worst pain imaginable.” Higher scores show greater pain intensity. Good test–retest reliability of NRS has been reported. STAI consists of 40 items. In this study, the 20 items assessing state anxiety were used. Each item of STAI is rated on a 4-point Likert scale. The scores range between 20 and 80, and higher scores indicate greater anxiety. The content validity of the Persian version of STAI was approved. Moreover, its reliability coefficient was reported to be 94.9 using Cronbach alpha. In the present study, the reliability coefficient was 0.81.

![Table 2](image-url)

<table>
<thead>
<tr>
<th>Pain Intensity</th>
<th>Before, Mean (SD)</th>
<th>0.5 Hour After, Mean (SD)</th>
<th>2 Hours After, Mean (SD)</th>
<th>Friedman Test, P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>5.72 (0.97)</td>
<td>5.51 (0.93)</td>
<td>4.72 (0.97)</td>
<td>27.63, 0.001</td>
</tr>
<tr>
<td>Control</td>
<td>5.66 (0.92)</td>
<td>5.87 (0.78)</td>
<td>5.72 (0.91)</td>
<td>2.47, 0.29</td>
</tr>
<tr>
<td>Effect size</td>
<td>-0.20</td>
<td>-0.20</td>
<td>-0.46</td>
<td></td>
</tr>
<tr>
<td>Z, P</td>
<td>-0.38, 0.70</td>
<td>-2.02, 0.04</td>
<td>-3.88, &lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

Z, Mann–Whitney U test.
Effect of Massage on Pain and Anxiety

As Table 3 and Supplemental Digital Content 1 (see Figure, http://links.lww.com/JOT/A485) show, before the intervention, no significant difference was observed between the 2 groups concerning anxiety ($Z = -1.27, P = 0.20$). However, after the intervention, Mann–Whitney $U$ test showed a significant difference between the intervention and control groups in terms of anxiety ($Z = -5.35, P < 0.001$).

DISCUSSION

This study showed that foot massage reduced pain intensity and anxiety in patients after a tibial shaft fracture surgery. Similar to this study, Eghbali et al$^{14}$ showed that pain intensity reduced as a result of a shallow massage on the healthy foot, hands, and upper shoulder after arthroscopic knee surgery in male patients. A systematic review on the effect of massage therapy on pain intensity and anxiety after surgery showed that this intervention may reduce postoperative pain and anxiety.$^{22}$ Similar to this study, another report has suggested that massage decreases acute postoperative pain.$^{23,24}$ Other studies have maintained that massage therapy reduces pain$^{17}$ and anxiety.$^{17,24,25}$ Furthermore, massage therapy has been reported to reduce pain$^{26}$ and stress,$^{27}$ improve patients’ mood, and relax them,$^{26}$ thus reducing their anxiety level.

Massage therapy as a feasible and acceptable intervention after surgery$^{28}$ reduced pain and anxiety in patients who underwent a tibial shaft fracture surgery; therefore, using this intervention is suggested in clinical practice, especially in an orthopaedic setting.

One of the limitations of this study was the short time of measurement for pain intensity and anxiety. The second limitation was a short clinical fracture care follow-up period, which must be a minimum of 12 months. Therefore, longitudinal studies with interventions and assessments for a longer duration are suggested. Furthermore, for increasing the generalizability of the trial findings, performing this study with a similar aim in other places in Iran and worldwide is suggested.

CONCLUSIONS

The results of this study showed that foot massage, as a feasible and acceptable method, reduces pain and anxiety in patients after tibial shaft fracture surgery.

ACKNOWLEDGMENTS

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TABLE 3. Comparison of the Mean Score of Anxiety in the Intervention and Control Groups Before and After the Intervention

<table>
<thead>
<tr>
<th>Variables</th>
<th>Intervention, Mean (SD)</th>
<th>Control, Mean (SD)</th>
<th>Effect Size</th>
<th>$Z_{11}, P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>54.72 (7.36)</td>
<td>57.48 (9.14)</td>
<td>-1.27, 0.20</td>
<td></td>
</tr>
<tr>
<td>After</td>
<td>42.84 (6.50)</td>
<td>58.36 (10.37)</td>
<td>-0.66, -5.35, &lt;0.001</td>
<td></td>
</tr>
<tr>
<td>$Z_{2}, P$</td>
<td>-4.90, &lt;0.001</td>
<td>-0.41, 0.68</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

$Z_{11}$, Mann–Whitney $U$ test; $Z_{2}$, Wilcoxon rank sum test.
REFERENCES


