Auricular Acupressure for Managing Postoperative Pain and Knee Motion in Patients with Total Knee Replacement: A Randomized Sham Control Study

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Background. Postoperative pain management remains a significant challenge for all healthcare providers. A randomized controlled trial was conducted to examine the adjuvant effects of auricular acupressure on relieving postoperative pain and improving the passive range of motion in patients with total knee replacement (TKR). Method. Sixty-two patients who had undergone a TKR were randomly assigned to the acupressure group and the sham control group. The intervention was delivered three times a day for 3 days. A visual analog scale (VAS) and the Short-Form McGill Pain Questionnaire were used to assess pain intensity. Pain medication consumption was recorded, and the knee motion was measured using a goniometer. Results. The patients experienced a moderately severe level of pain postoperatively (VAS 58.66 ± 20.35) while being on the routine PCA. No differences were found in pain scores between the groups at all points. However, analgesic drug usage in the acupressure group patients was significantly lower than in the sham control group (P < 0.05), controlling for BMI, age, and pain score. On the 3rd day after surgery, the passive knee motion in the acupressure group patients was significantly better than in the sham control group patients (P < 0.05), controlling for BMI. Conclusion. The application of auricular acupressure at specific therapeutic points significantly reduces the opioid analgesia requirement and improves the knee motion in patients with TKR.

1. Introduction

Knee osteoarthritis frequently occurs in elderly people. The overall prevalence of knee osteoarthritis is 23.9%, occurring in 21.0% of men and 27.3% of women [1]. Knee-replacement surgery is frequently performed and is highly successful with respect to pain relief and the improvement in knee function in people with advanced knee osteoarthritis [2]. Postoperatively, patients undergoing total knee replacement would experience significant pain, which can limit their progression in the range of knee motion and ambulatory status.

Despite the development of new pain control methods and medication and the adoption of guidelines for pain care by many hospitals, postoperative pain is still a problem for many patients. A substantial proportion of total knee
Patients were excluded if they suffered from pain or injuries in the ears, had a history of neurological disorders that could alter their perception of pain, a prior experience with auriculotherapy, malignant tumors, a serious chronic illness, mental illness, or drug/alcohol addiction, or were unable to give consent or follow instructions during the data collection process.

All of the patients received an operation under standardized general anesthesia protocols. The patients received routine pain management at the end of the operation: the intravenous PCA was connected to an IV line and set to deliver a bolus of 1 mg morphine with a lockout interval of 5 minutes and a 4-hour maximum morphine dose of 10 mg.

2.1. Experimental Procedures. Patients who met the study criteria were interviewed by the investigator before the operation; the purposes of the study were explained, and written consent to participate in the study was then obtained. Throughout the study period, one acupressure therapist performed the auricular acupressure, and the outcome data were collected by a research assistant who had been trained and was blinded to the patient’s group. The physicians, anesthesiologists, and nurses had no previous knowledge of acupressure and were blinded to the patients’ group allocation. The data collection processes are shown in Figure 1.

The study, which was conducted at a regional teaching hospital in central Taiwan, used a sham control group and double-blinded experimental design. Sixty-two patients were recruited in our study during an eight-month period. Based on computer-generated codes, block randomization was used with a block size of 4. The patients were randomly assigned into the auricular acupressure or sham control groups. The auricular acupressure therapy was delivered by the therapist, who was an advanced practice nurse and had been accredited for practicing acupressure. The auricular acupressure involved embedding the magnetic beads within skin-colored adhesive tape that was placed on the auricular acupoints and retained in situ for 3 days (Figure 2). The choice of Shenmen (TF4) and subcortex (AT4) acupoints was based on clinical reports [15–18, 21] and the TCM physician’s recommendation. Acupressure then was applied by repeatedly pressing the acupoints with the fingertips for 3 minutes per point, 3 times per day (9 AM, 1 PM, 5 PM). The last treatment was given on the third day after surgery at 5 PM. To validate the auricular acupressure, two Chinese medicine practitioners confirmed the acupoints and the acupressure protocol.

The patients in the sham control group received regular care and also received the same skin-colored adhesive tape placed on the acupoints but did not receive any massage or acupressure. The sham control patients were given auricular acupressure after the data collection was completed.

The sample size was estimated based on the data of the pilot study. With an effect size $f$ of 0.84, an $\alpha$ error probability of 0.05 and data collection performed in triplicate, a sample size of 62 would achieve statistical power up to 0.90.
The pain assessment was conducted using the visual analog scale (VAS) and the Short-Form McGill Pain Questionnaire (SF-MPQ), both of which have good reliability [22]. The VAS was used to measure the pain perceived by the patients through a vertical line scale ranging from 0 to 100 mm. A score of 0 indicates “not painful at all”, and a score of 100 indicates “the most severe pain ever experienced”. Higher scores indicate more severe degrees of perceived pain [23]. The Cronbach’s α was 0.83 in this study.

The SF-MPQ was modified from the MPQ by Melzack in 1987 [24]. The scale covers the nature of pain and the quantity of pain. The sensory dimension comprises 11 questions, the affective dimension comprises 4 questions, and the present pain intensity (PPI) dimension comprises one question. The SF-MPQ has been used to assess postoperative pain, labor pain, bone pain, and muscle pain. Similar to the McGill Pain Questionnaire (MPQ), the short form of the questionnaire has good validity, and the correlation between the two reaches 0.65~0.94 [25]. This study adopted the Chinese version of the SF-MPQ, which has been shown to have good internal reliability (Cronbach’s α range, 0.78 to 0.83) [26]. Cronbach’s α was 0.76 in this study.

The range of motion is measured with the flexion mobility of the knee at day 3 after the surgery using the goniometer integrated in the dynamometer [27]. Non-weight-bearing passive ROM values were obtained with the patient in the supine position to allow free hip flexion.

2.2. Statistical Analysis. Data management and analyses were conducted using the SPSS for Windows statistical package, version 17.0. The patients’ demographic profiles and baseline data were compared using the t-test, χ², or one-way analysis of variance (ANOVA). A generalized estimation equation (GEE) modeling was applied to investigate the effect of auricular acupressure for the outcomes of pain and opioid consumption. A t-test was used to compare differences in knee motion between the acupressure and sham control groups. A P value of less than 0.05 was considered to indicate statistical significance.

3. Results

A total of 62 patients completed the study, 53 women and 9 men, with a mean age of 70.98 (range 46–88) years. The operations included 31 left knees and 31 right knees and were performed by 2 surgeons. There were no differences between the acupressure and sham control groups in terms of the demographic and clinical characteristic data obtained at the baseline (all P > .05) (Table 1). None of the patients who received auricular acupressure showed any complications or adverse reactions after the therapy.

3.1. The Changes in the Pain Scores. The descriptive data of the postoperative pain scores (VAS-pain and Short-form McGill Pain Questionnaire) reported by the patients are shown in Table 2. Overall, the patients experienced moderately severe pain on the 1st day after surgery (VAS 58.66 ± 20.35) while being on the routine patient-controlled analgesia. However, the pain scores decreased gradually over time (Figure 3) but did not reach significant between-group differences in either of the pain scores (P > .05).

3.2. The Changes in Pain Medication Use. The results of the analgesic (morphine) usage of the patients are summarized in Figure 4. The analgesic drug usage (38.49 ± 15.53 mg of morphine) in the acupressure group patients was significantly lower than in the sham control group patients (53.07 ± 19.90 mg) (P < 0.05). Additionally, after controlling for BMI, age, and pain scores (VAS) in the generalized estimated equation model analysis, analgesic drug consumption in the acupressure group patients remains significantly lower than in the sham control group (P = .002) patients over time (Table 3). The dose of morphine in the sham control group was 8.38 times higher than in the acupressure group.
Table 1: Demographic and clinical characteristics of the study groups.

|                      | Acupressure (n = 31) | Sham control (n = 31) | P value (between group) |
|----------------------|----------------------|-----------------------|-------------------------|
| Age^a (range 46–88)  | 71.23 ± 7.09         | 70.74 ± 8.09          | .803                    |
| BMI^b                | 27.19 ± 3.08         | 28.73 ± 4.14          | .103                    |
| Gender^b             |                      |                       |                         |
| Male                 | 3 (9.7)              | 6 (19.4)              | .473                    |
| Female               | 28 (90.3)            | 25 (80.6)             |                         |
| Religious belief^b   |                      |                       |                         |
| Yes                  | 27 (87.1)            | 23 (74.2)             | .335                    |
| No                   | 4 (12.9)             | 8 (25.8)              |                         |
| Marital status^b     |                      |                       |                         |
| Married              | 18 (58.1)            | 23 (74.2)             | .283                    |
| Widowed/separated    | 13 (41.9)            | 8 (25.8)              |                         |
| Education^b          |                      |                       |                         |
| Illiterate           | 11 (35.5)            | 9 (29.0)              | .786                    |
| Primary school or higher | 20 (64.5)         | 22 (71.0)             |                         |
| Occupation^b         |                      |                       |                         |
| No                   | 29 (93.5)            | 24 (77.4)             | .147                    |
| Yes                  | 2 (6.5)              | 7 (22.6)              |                         |
| Joint replacement history^a | 5 (16.1)        | 4 (12.9)              | 1.00                    |
| No                   | 26 (83.9)            | 27 (87.1)             |                         |
| Surgical site^b      |                      |                       |                         |
| Left                 | 14 (45.2)            | 17 (54.8)             | .612                    |
| Right                | 17 (54.8)            | 14 (45.2)             |                         |

^aIndependent t-test; ^bChi-Square test.

Table 2: Changes in pain scores between the groups over time.

|                      | All (n = 62)                  | Acupressure (n = 31) | Sham control (n = 31) | P value |
|----------------------|-------------------------------|----------------------|-----------------------|---------|
|                      | Mean ± SD                     | Mean ± SD            | Mean ± SD             |         |
| VAS                  |                               |                      |                       |         |
| Baseline             | 58.66 ± 20.35                 | 57.00 ± 17.83        | 60.32 ± 22.77         | .525    |
| Posttest 1           | 46.02 ± 18.32                 | 46.87 ± 17.05        | 45.16 ± 19.77         | .717    |
| Posttest 2           | 36.77 ± 16.02                 | 36.45 ± 13.74        | 37.10 ± 18.25         | .876    |
| Posttest 3           | 27.58 ± 13.96                 | 27.42 ± 12.24        | 27.74 ± 15.70         | .928    |
| SF-MPQ               |                               |                      |                       |         |
| Baseline             | 12.85 ± 5.93                  | 12.26 ± 5.79         | 13.45 ± 6.11          | .433    |
| Posttest             | 5.18 ± 3.84                   | 5.16 ± 4.08          | 5.19 ± 3.66           | .974    |
| Pain PPI             |                               |                      |                       |         |
| Baseline             | 2.95 ± 1.02                   | 2.74 ± .89           | 3.16 ± 1.10           | .104    |
| Posttest             | 1.34 ± .63                    | 1.23 ± .50           | 1.45 ± .72            | .157    |

VAS: visual analog scale for pain; SF-MPQ: Short-Form McGill Pain Questionnaire; Pain PPI: present pain intensity score of SF-MPQ.

3.3. The Changes in the Passive Flexion Motion of the Knee.
On the 3rd day after surgery, the passive knee flexion motion in the acupressure group patients (71.68 ± 6.90°) was significantly better than in the sham control group patients (66.94 ± 7.15°) (P = .01). The results of Pearson’s correlation analysis found a negative correlation between the knee flexion motion and BMI (P < 0.05). Therefore, further regression analysis was conducted, and after controlling for BMI, the results remained significant between the groups (P = .02).
allowing patients to have a better compliance with the treatment involving a nonpharmacological modality may offer some benefits in the management of postoperative pain in TKR patients. Novel findings of Usichenko et al. [15–17] demonstrated that auricular acupuncture is more effective than the acupressure group. This finding is consistent with that of previous studies, which showed that auricular acupuncture is more effective in managing postoperative pain than traditional analgesics [14, 15]. Furthermore, our findings corresponded with previously reported results [1] and those of Norkin et al. [27], who reported that patients are still in pain while being treated with analgesic drugs and techniques, indicating that the management of postoperative pain remains a challenge for medical practitioners. Notably, our study had no actual placebo group for the patients; we used a randomized sham control design and used adhesive tape on the acupoints as the sham control. We also provided acupressure to the sham control group patients at the end of this study. With this design, all participants eventually received the therapeutic auricular acupressure. Our design may avoid the ethical dilemma of withholding potential benefits for half of the participants. Noticeably, our study had no actual placebo group for comparing the study effects. According to TCM theory, the body contains 14 meridians (“Jing”, like boulevards) that bear countless branches (“Luo”, like byways). The meridians are densely distributed, especially in the ear, massage anywhere on the body can produce the same effects. According to TCM theory, finding a body site without the influence of any Jing and Luo would be difficult. Considering that most of the meridians are densely distributed, especially in the ear, massage anywhere on the body can produce the same therapeutic effect [28]. Consequently, using a nonacupoints

4. Discussion

Our patients reported postoperative pain as moderately severe during the 1st day (baseline) following TKR while the patients were on PCA for pain management. This result corresponded with previously reported results [1] and those of Norkin et al. [27], who reported that patients are still in pain while being treated with analgesic drugs and techniques, indicating that the management of postoperative pain remains a challenge for medical practitioners. Subsequently, alongside the conventional opioid analgesics, an adjuvant treatment involving a nonpharmacological modality may offer some benefits in the management of postoperative pain in TKR patients.

Similar to acupuncture, we found that 3 days of auricular acupressure can significantly lower the postoperative opioid consumption after a total knee replacement surgery. Our results showed that the morphine consumption in the sham control group patients was 8.38 times higher than that in the acupressure group. This finding is consistent with that of previous studies, which showed that auricular acupuncture is effective in managing postoperative pain [14, 15]. Notably, our study had no actual placebo group for the patients; we used a randomized sham control design and used adhesive tape on the acupoints as the sham control. We also provided acupressure to the sham control group patients at the end of this study. With this design, all participants eventually received the therapeutic auricular acupressure. Our design may avoid the ethical dilemma of withholding potential benefits for half of the participants. Noticeably, our study had no actual placebo group for comparing the study effects. According to TCM theory, the body contains 14 meridians (“Jing”, like boulevards) that bear countless branches (“Luo”, like byways). The meridians are densely distributed, especially in the ear, massage anywhere on the body can produce the same therapeutic effect [28]. Consequently, using a nonacupoints...
placebo group in this study may be inappropriate. Thus, our design has no true placebo group, and the sham control group was used to try to distinguish the auricular acupressure effects from the psychological effects.

A potential limitation of our research is that those who chose to be involved in the trial were limited to one hospital, and the findings may therefore not be indicative of the changes likely to occur with the general TKR population. Furthermore, the followup period of 3 days after the TKR surgery was short, and we have no way to determine the long-term effects of auricular acupressure. Furthermore, the dose of acupressure may have been inadequate; for example, more frequent treatments or a different treatment protocol may have generated different results. Given that reasonable evidence on the course effectiveness has been established in the current study, further research should focus on longer-term followup and collecting data from multiple centers to determine whether the changes and positive effects of acupressure are maintained over time.

In conclusion, a program of auricular acupressure applied to therapeutic auricular acupoints significantly reduces the opioid analgesic consumption and improves the passive range motion of the knee postoperatively after total knee replacement. However, both groups of patients experienced a similar degree of pain, based on their reported scores, while on the routine PCA for pain management.

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