The Effect of Auricular Acupressure on Sleep Disturbance Among Patients With Leukemia

A Feasibility Study

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Auricular acupressure (AA) is widely used in East Asia and Europe to manage patients with sleep disturbance. This feasibility study was performed to demonstrate the potential of AA for sleep disturbance in patients with leukemia. Thirty-two patients with leukemia with poor sleep quality received AA 3 times a day for a total of 4 weeks. The Pittsburgh Sleep Quality Index (PSQI) was used to assess sleep quality at baseline, at a 2-week intervention, and after a 4-week intervention. Compared with baseline scores, PSQI scores and the use of sleep medicine were significantly improved at week 2 and week 4 ($P < .05$). As a potential safety therapy, AA could be an alternative or complementary intervention to improve sleep quality for patients with leukemia with sleep disturbance.

KEY WORDS: *auricular acupressure*, *leukemia*, *sleep disturbance* *Holist Nurs Pract* 2020;34(2):103–112

Sleep disturbance is a common health-related issue and a common side effect in patients with leukemia. It is characterized by complaints of difficulty falling asleep, difficulty remaining asleep, or early morning waking that lasts for at least 1 month and causes significant impairment of patients' daily activities.[1] According to a recent study in the United States, the incidence of sleep disturbance among patients with leukemia is relatively high (30%-50%) and this risk is still on the rise.[2] Patients with leukemia suffering from sleep disturbance are prone to pain, fatigue, dizziness, nervousness, attention disorders, and sleeping pill dependence.[2-4] Uncontrolled sleep disturbances can contribute to compromised immune functionality and reduced patient survival after cancer diagnosis.[5,6] Sleep disturbance may also impair the normal quality of life of patients with leukemia and result in severe psychological symptoms, including anxiety and stress.[7] Therefore, prevention of sleep disturbance among patients with leukemia is of the utmost importance.

Recent studies have recommended that administration of hypnotic pharmaceutical agents may have beneficial effects on sleep quality management for patients with leukemia.[8] International guidelines recommended only short-term use of such agents for the treatment of insomnia.[9] Moreover, these drugs are frequently associated with undesirable side effects and with elevated risks of serious adverse events (AEs), including daytime drowsiness, elevated fall and fracture risks, and hypnotic medication dependence or tolerance.[2] Therefore, patients with leukemia with sleep disturbance often tend to seek complementary and alternative medicine (CAM) therapies to help manage their sleep quality.[10]

Auricular acupressure (AA) is an important form of CAM. It is a technique that involves *Semen vaccariae* (*wang bu liu xing*) seeds or magnetic pellets applied with an adhesive patch to chosen acupuncture points on the ears.[11] Compared with acupuncture, AA

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is a noninvasive therapy that is often more accessible for recipients. In 1990, AA was considered a type of microacupuncture that may have positive effects on the "whole human system."[12] Western neurophysiological examinations have revealed that pathological changes in peripheral tissues can eventually lead to dysfunctional neural firing patterns in the corresponding neural microcircuits in both the brain and the spinal cord.[13] Recently, relevant research has demonstrated that AA can stimulate the production of melatonin within the endocrine system, restoring neurohormone levels and normalizing sleep cycles.[14,15] In addition, other studies revealed that AA may downregulate hypothalamic γ-aminobutyric acid (GABA) and GABA type A receptors and increase levels of β-endorphin and nitric oxide in the brain and blood.[16-18] Moreover, organization of the connections between peripheral nerves and the central nervous system was controlled by sites in the sensory thalamus. Stimulation of acupuncture points may serve to suppress the auricular branches of the vagus nerve in the sensory thalamus, thereby modulating the autonomic nervous system, which can reduce both blood pressure and heart rate and increase heart rate variability, eventually improving sleep quality.[19-22] This conceptual framework thus outlines how AA can activate specific brain structures and consequently affect other variables within the system including the endocrine, endorphinergic, and autonomic nervous systems (Figure 1).

Previous studies have demonstrated that AA may alleviate sleep disturbance in patients with various chronic illnesses. However, evidence of the effectiveness of AA in treating sleep disturbance among patients with cancer is more limited.[23] In addition, there have been no studies conducted in which AA was used to improve sleep quality in patients with leukemia. Hence, the aim of this study was to investigate the effects of AA on sleep quality in patients with leukemia.

LITERATURE REVIEW

Effects of AA on different disorders associated with sleep disturbance

Researchers have examined the effectiveness of AA for improving the sleep quality of patients with a range of disorders. Cha et al[24] investigated how AA altered sleep quality among 67 middle-aged women in South Korea and identified statistically significant differences between AA-treated individuals and controls in terms of sleep status. Chueh et al[25] similarly explored the effects of AA on 32 Chinese nursing students with insomnia and reported a significant improvement in the Pittsburgh Sleep Quality Index (PSQI) scores in the experimental group as compared with the control group. Moreover, a nonrandomized, single-arm, feasibility study

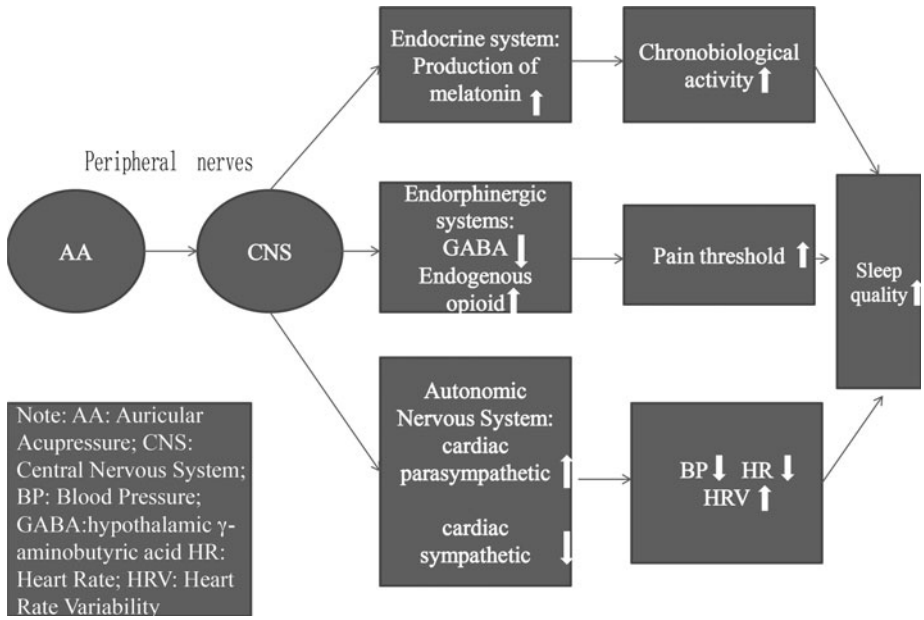

FIGURE 1. Theoretical framework of auricular acupuncture on sleep disturbance among patients with leukemia.

evaluated a short course of AA for severe insomnia in patients undergoing maintenance hemodialysis. The findings suggested that AA provided a short-term benefit, improving total sleep time and sleep latency.[26] Yeh et al[27] applied AA therapy weekly for 4 weeks to investigate its effect on insomnia in patients with chronic back pain. The results showed that AA significantly decreased insomnia in these patients. Furthermore, in a systematic review and meta-analysis by Yeung et al,[28] acupressure, reflexology, and AA trials all showed evidence of being effective interventions for treating primary insomnia.

Addressing sleep disturbance in patients with cancer

Although no previous studies had applied AA to patients with leukemia suffering from sleep disturbance, it has been applied in the context of other types of cancer. Hughes et al[29] conducted a nonrandomized, single-arm, feasibility study on 7 cancer survivors suffering from sleep disturbance (5 patients with breast cancer and 2 patients with colorectal cancer) who received a 5-week treatment course consisting of pressure on 6 AA points and found significant improvements in global PSQI scores and on scores of the Athens Insomnia Scale in these treated patients ($P < .01$). Yeh et al[30] conducted a similar study on patients with breast cancer receiving chemotherapy, and they found that after a 5-week AA course, PSQI scores of these patients dropped significantly ($P < .05$). In the Yeh et al[30] study, subscale scores also improved significantly; for example, sleep quality ($P < .05$), habitual sleep efficiency ($P < .05$), and sleep latency ($P < .01$) all changed in a desirable direction during AA treatment. Moreover, Fan et al[31] provided AA (involving TF4, CO15, and AT4) to 120 patients with breast cancer and found that participants in the study group exhibited greater improvements in the usage of sleep medication than did the control group after 2 weeks of treatment ($P < .05$).

METHODS

Ethical considerations

This research was conducted in compliance with the Declaration of Helsinki and was approved by the institutional review board of the affiliated hospital of Soochow University (IRB no. SDUIRB-10102-B).

Trial design

This was a quasi-experimental, single-arm, pre/posttest design. Pre- and posttest surveys were conducted before and after the experiment and at 2 weeks, respectively, to measure the sleep quality of patients with leukemia.

Sample size

Sample-size power calculations were completed by a statistician in a blinded manner. The statistician used the G* power version 3.1.5 software package (Grant Devilly, Victoria, Australia) to calculate the needed number of samples, setting one-sided significance level = .05, power = 0.80, and predicted effect size = 0.50, resulting in the calculated numbers of 28 participants.[30] Assuming a 20% chance of patient dropout during the study, the total numbers of participants necessary for the study was determined to be 35.

Participants

In this study, a total of 70 patients with leukemia attending the Hematology clinic unit of the affiliated hospital of Soochow University, from December 2016 to June 2017, were recruited. Inclusion criteria were as follows: (1) patients 18 years or older, with a new diagnosis of leukemia; (2) able to undergo 4 weeks of intensive induction chemotherapy; (3) able to read and understand at a basic educational level; (4) fully conscious; and (5) scored 5 or more on the PSQI. Exclusion criteria were as follows: (1) comorbid conditions (congestive heart failure, connective tissue disease, other types of cancer, etc); (2) psychiatric disorders and an inability to clearly express their feelings; (3) undergoing planned hospitalization for less than 4 weeks/not completing initial chemotherapy; and (4) presence of severe physical symptoms (chronic back pain, chronic musculoskeletal pain, itchy skin, etc) that are obvious causes of insomnia. Finally, 35 participants were enrolled as eligible study participants (10 did not meet the inclusion criteria and 25 declined to participate in this study). Informed written consent was obtained from each participant.

Interventions

In this study, standard AA procedures were performed. After reviewing published literature[32] and

consulting with 3 traditional Chinese medicine (TCM) experts and a TCM nursing specialist with more than 20 years of AA clinical practice experience, the research team selected 5 specific acupuncture points: shen men (TF4), sympathetic autonomic (AH6a), heart (CO15), subcortex (AT4), and endocrine (CO18), as indicated in Figure 2.

The Chinese Standard Ear-Acupoints Chart, which is recognized by the World Health Organization, is used to identify AA points[12] (Figure 2).

The 2 practitioners applying AA in this trial were research assistant (RA) nurses who had completed a master's degree TCM nursing specialist training course provided by a licensed TCM university. After routine disinfection of the region surrounding each selected acupuncture point with 75% isopropyl alcohol, seeds of *S vaccariae* (1.5 mm in diameter; surface: smooth; color: black [Auricular Medicine Instrument Co, Ltd, Hoover, Alabama]) were embedded on the chosen acupuncture points using adhesive patches (1.0 × 1.0 cm). Based on previous research and consultation with TCM experts,[33,34] the nurses used their fingertips to apply intermittent AA (pressure was applied every 0.5 seconds with a tolerable force level, resulting in slight soreness, numbness, swelling pain, and a *qi* sensation) to each AA point for at least 1 minute, 3 times per day (around 9 AM, 5 PM, and 9 PM), for a total of 4 weeks. If adhesive patches detached at any time during the study, they were replaced without delay by RA nurses. To avoid the development of any skin lesions caused by sustained adhesion of these patches to one ear, adhesive patches were replaced every 2 to 3 days. When replacing these adhesive patches, the RA nurses also recorded patients' compliance and accuracy in their AA performance.

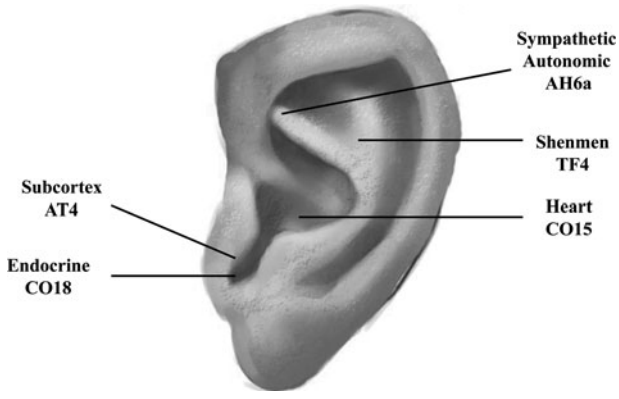

FIGURE 2. Map of auricular acupuncture points showing the location of acupuncture points selected in this trial.

Instruments

The demographic variables recorded in this study were as follows: gender, age, marital status, education level, occupation, smoking history, medical insurance, diagnosis, and chemotherapy regimens.

The PSQI is an internationally validated questionnaire used to determine the sleep quality of patients with leukemia.[35] This questionnaire consists of 7 dimensions (subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction.). Each dimension is assigned a score ranging from 0 to 3, with total scores ranging from 0 to 21. Higher scores indicate more severe decreases in sleep quality; a score of less than 5 indicates favorable sleep quality, whereas a score of 5 or more indicates poor sleep quality. In this study, we obtained permission to apply the PSQI from Professor Buysse by e-mail. In addition, the Chinese version of the PSQI proposed by Professor Zheng was employed[36] and the Cronbach α of the PSQI, which was previously reported to be between 0.80 and 0.90, was equal to 0.856 in the present study. PSQI scores were evaluated at baseline, after the 2-week intervention, and after the full 4-week intervention. Moreover, the quantity of sleep medications used per week by the patients with leukemia with poor sleep quality was recorded at baseline and after a 4-week intervention.

Data analysis

Data analysis was carried out using IBM SPSS version 20.0 software (SPSS Inc, Chicago, Illinois) for Windows. Descriptive statistics of the mean (standard deviation [SD]) for continuous variables and frequency (percentage) for categorical variables were calculated to summarize the demographic characteristics of patients with leukemia suffering from sleep disturbance. PSQI scores were compared at baseline and at 2 and 4 weeks using intention-to-treat (ITT) and repeated-measures analysis of variance (ANOVA). Bonferroni adjustments were used to account for multiple testing comparisons. The χ^2 and Fisher exact tests were used to assess the amount of sleep medication used at baseline and after a 4-week intervention. A value of $P < .05$ was considered statistically significant.

Safety assessment

To detect AEs and other complaints, all patients with leukemia had follow-up visits with an attending

physician every 5 days. All patients with leukemia were asked to report any AEs, especially local skin irritation, discomfort, and dizziness.

RESULTS

From December 2016 to June 2017, a total of 35 patients with leukemia with poor sleep quality were enrolled in this study. Of these, 32 completed and returned all follow-up measures (at week 2 and week 4). The total dropout rate was 8.6%, with 66.7% being due to a declination to participate further. Two patients were unable to finish the first 2 weeks of treatment because of mild discomfort and declined to participate further, whereas 1 participated for more than 2 weeks but was unable to finish the 4-week study course. Figure 3 shows the Consolidated Standards of Reporting Trials flow chart for this study.

Thirty-two patients were enrolled as eligible participants. The mean patient age was 38.60 (SD = 2.35) years. Most participants were female (62.5%), had a high school diploma education level (59.37%), and were nonsmokers (62.5%) at the time of the study. All patients were married. Half of the participants had a diagnosis of acute myeloid leukemia (50%). With regard to chemotherapy regimens (46.88%), the combination of idarubicin + cytarabine was the most frequent modality used in these patients with leukemia. Baseline patient characteristics are summarized in Table 1.

Cronbach α reliability coefficient of the PSQI scale, used in our study, was found to be 0.856. To account for the dropout in participation, we conducted an ITT analysis by replacing missing values. In our study, the mean PSQI global score of patients with leukemia was 6.32 (SD = 0.25) before the application of AA. Compared with baseline scores, total PSQI scores were significantly improved at both week 2 and week 4 after AA treatment as determined by ANOVA ($P < .05$) (Table 2 and Figure 4). Moreover, significant differences were noted in sleep latency and sleep quality domains of the PSQI ($P < .01$) (Table 2 and Figure 4). After AA therapy, fewer patients were taking more than 2 sleep medications daily ($P < .05$) and the average weekly dose of sleep medications was also significantly reduced ($P < .01$) (Table 3). No significant AEs were observed during the course of this study. Only one patient reported mild discomfort during AA therapy at the week 2 follow-up point of this study (Figure 3).

DISCUSSION

According to these results, the mean PSQI global scores of patients with leukemia were greater than 4 before

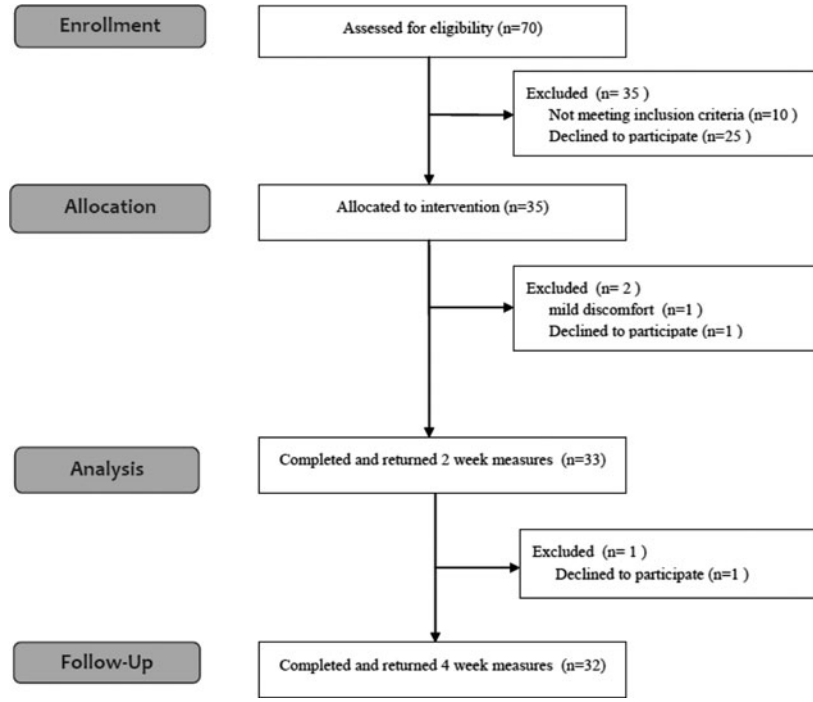

FIGURE 3. Consolidated Standards of Reporting Trials flow chart.

TABLE 1. Demographic Characteristics of the 32 Study Patients

Characteristics	Value
Gender, n (%)	
Female	20 (62.5)
Male	12 (37.5)
Age, mean(SD), y	38.6 (2.35)
Marital status, n (%)	32 (100)
Education level, n (%)	
High school diploma	19 (59.37)
Community college degree	5 (15.62)
Undergraduate studies	5 (15.62)
Postgraduate studies	2 (6.25)
Unknown	1 (3.14)
Smoking history	
Previous only	7 (21.88)
Current	5 (15.62)
Never smoked	20 (62.5)
Medical insurance covered, n (%)	20 (62.5)
Diagnosis, n (%)	
Acute lymphocytic leukemia	12 (37.5)
Acute myeloid leukemia	16 (50)
Mixed phenotype acute leukemia	4 (12.5)
Chemotherapy regimens, n (%)	
IA regimen[a]	15 (46.88)
IAVP regimen[b]	13 (40.62)
IOLP regimen[c]	4 (12.5)

[a]IA regimen: idarubicin + cytarabine.
[b]IAVP regimen: idarubicin + cytarabine + vincristine + dexamethasone.
[c]IOLP regimen: idarubicin + vindesine +L-asparaginasum + dexamethasone.

the 4-week AA treatment, indicating poor overall sleep quality in these patients (Table 2). Yeh et al[27] found that the mean global PSQI score of patients with leukemia undergoing chemotherapy was 12.50 (SD = 1.65), indicating a poor sleep quality, consistent with our findings. Moreover, previous research suggests that average PSQI global scores of patients with leukemia on maintenance chemotherapy are higher than those of adult inpatients and healthy populations.[12] Thus, sleep disturbance is common among patients with leukemia.

This study examined the feasibility of using a 4-week AA therapy to target and alleviate sleep disturbance in patients with leukemia. Our findings demonstrate that a 4-week AA regimen based on TF4, AH6a, CO15, AT4, and CO18 improved total PSQI scores for patients with leukemia ($P < .05$; Table 2 and Figure 3). In addition, differences in the mean sleep latency and sleep quality PSQI component scores were statistically significant ($P < .05$; Table 2 and Figure 3). This result was consistent with that of a previous study that found that AA may have a beneficial effect on global PSQI scores and a range of sleep outcomes (sleep quality, habitual sleep efficiency, and sleep latency) for patients with cancer suffering from sleep disturbance.[29,30] Considering the fact that all of the patients with leukemia in our study have received chemotherapy and most of them use regular sleep medication (Table 3), this is consistent with the past finding that therapeutic chemotherapy is one of the most common causes of sleep difficulties in patients with cancer.[28] Most patients with cancer eventually need to depend on sleep medications to alleviate their sleep disturbance.[30] These findings, partly consistent with our studies, suggest that AA may be a useful therapeutic approach toward discontinuing or minimizing the use of sleep medications for patients with cancer suffering from poor sleep quality.

TABLE 2. Repeated-Measures Analysis of Variance of the PSQI at Baseline and at Week 2 and Week 4[a]

Variable	Baseline, Mean (SD)	2 wk, Mean (SD)	4 wk, Mean (SD)	*F*	*P*
Daytime dysfunction	1.40 (0.10)	1 (0.15)	0.84 (0.06)	0.60	.75
Sleep latency	2.52 (0.06)	2.27 (0.07)	1.52 (0.10)	6.66	<.01[b,c,d]
Sleep disturbance	2.36 (0.14)	1.73 (0.25)	1.36 (0.09)	0.47	.84
Sleep duration	1.96 (0.31)	1.56 (0.17)	1.44 (0.07)	1.22	.35
Habitual sleep efficiency	1.60 (0.39)	1.19 (0.47)	0.96 (0.54)	1.97	.13
Sleep quality	0.72 (0.42)	0.49 (0.21)	0.28 (0.07)	2.79	.04[b,c,d]
Use of sleeping medication	0.73 (0.10)	0.68 (0.12)	0.45 (0.23)	0.29	.95
Global score	11.29 (0.23)	8.92 (0.15)	6.85 (0.05)	3.09	.03[b,c,d]

Abbreviation: PSQI, Pittsburgh Sleep Quality Index.
[a]Bonferroni corrected post hoc analysis is significant between weeks.
[b]Baseline and 2 weeks.
[c]Baseline and 4 weeks.
[d]2 weeks and 4 weeks.

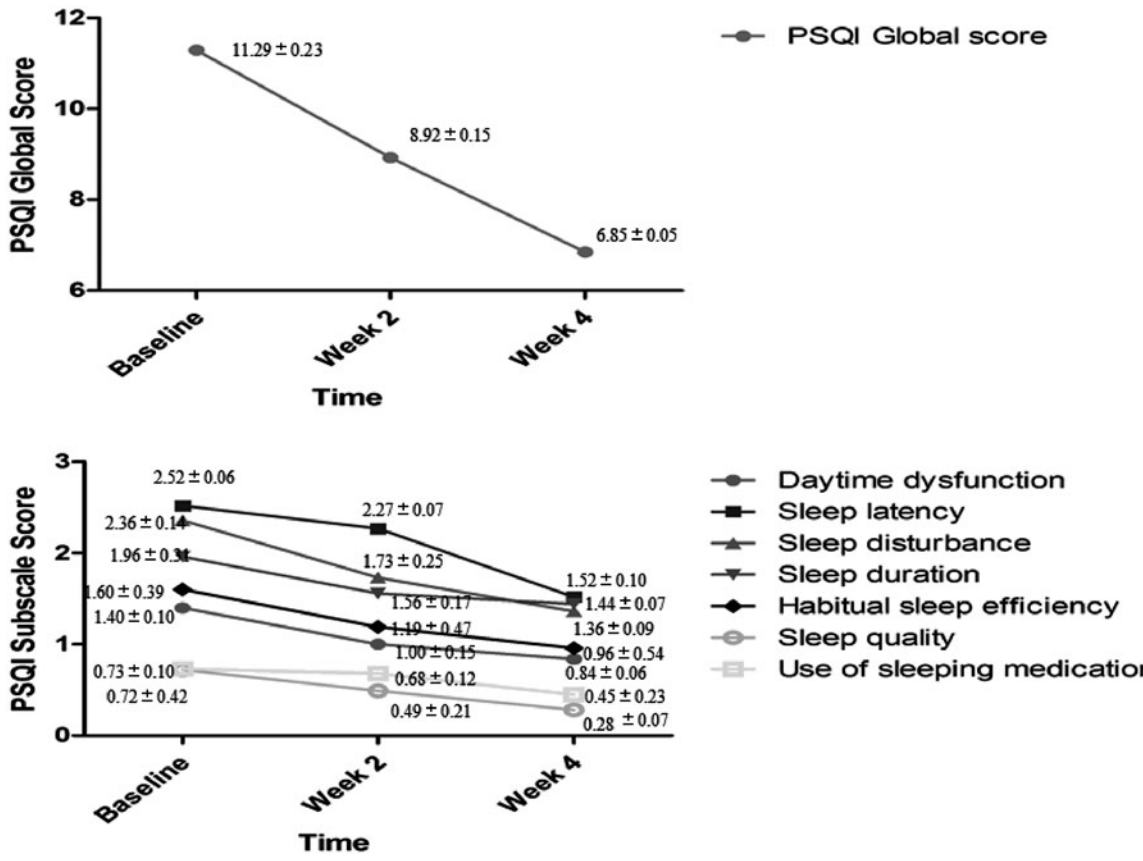

FIGURE 4. Changes in PSQI subscale and total scores over time. PSQI indicates Pittsburgh Sleep Quality Index.

Assuming that AA is a beneficial treatment option for patients with leukemia with sleep disturbance, the possible mechanisms of action are of interest. From TCM *zang-fun* perspectives, sleep disturbances are mainly due to dysfunction of the heart.[37] Both the selected Shenmen (TF4) and heart (CO15) acupuncture points were related to the heart. Thus, stimulation of these 2 acupuncture points can relax the spirit of patients with leukemia and thereby improve their sleep quality. The other selected acupuncture points—sympathetic autonomic (AH6a), subcortex (AT4), and endocrine (CO18)—may effectively help with self-modulation of internal organs, release internal body *Qi*, stimulate metabolism, promote blood circulation, and balance *Yin* and *Yang*. Therefore, the aforementioned TCM may partly account for the possible mode of action whereby AA alleviates sleep disturbance, providing a better understanding of the mechanisms of AA.

TABLE 3. Sleep Medication Use Before and After the Intervention

Variable	Pre-AA	Post-AA	*P*
Dose, n			
2 pills per day	9	0	.03[a]
1.5 pills per day	2	2	
1 pill per day	15	10	
0.5 pill per day	2	1	
Weekly dose (pills), mean (SD)	6.32 (0.25)	3.87 (0.12)	<.01[b]

Abbreviation: AA: auricular acupressure.
[a]Fisher exact test.
[b]Paired *t* test.

Inclusion of a placebo or sham AA group that is comparable with the actual effects of AA may be crucial to future studies. Two sham AA methods have been proposed for AA trials (light touch of acupuncture points or the selection of sham acupuncture points) that may achieve patient blinding.[38,39] Unfortunately, with regard to the former sham method, most participants are able to identify the type of AA therapy they received because light touches at acupuncture points could be easily identified as being an inactive treatment.[40] The main drawback of the latter AA sham method (the selection of sham acupuncture points) was the lack of an essential TCM meridian and channel theory of AA.

For example, based on the connection between AA points and the skin surface in TCM *zang-fun* theory, in several studies, lung AA points may have a positive effect on pain reduction during incisions.[41] In other words, acupressure at a sham acupuncture point may still positively or negatively affect the outcomes of an actual intervention. Thus, no completely reliable AA sham method currently exists, and we did not include sham AA in our study at this time. In the future, adequate sham AA methods must be established.

The safety of AA is another important issue that must be further researched. Probable AEs related to AA such as local skin irritation, pain, and dizziness were all commonly reported in a previous systematic review.[42] In our research, aside from mild discomfort, no serious AA-related AEs were reported by patients enrolled in this study (Figure 1). This is consistent with previous studies that have reported that AA therapies do not cause serious AEs when used on appropriate recipients.[29,30] Therefore, AA may be considered a relatively safe intervention. In the future, our trials should assess additional details relating to any AA-associated AEs in larger-sample populations.

IMPLICATIONS FOR NURSING PRACTICE

A majority of patients with leukemia receiving chemotherapy suffer from varying levels of sleep disturbance severity. Pharmaceutical hypnotics and other therapies aimed at remedying these are frequently associated with undesirable side effects. Patients with leukemia expect holistic care including the use of AA to promote optimal sleep health. It is also imperative that the needs of patients be met effectively by implementing AA to minimize sleep medication use and promote sleep quality.

Nurses play an active role in the identification and management of the sleeplessness commonly seen in patients with leukemia. This study has several important implications for nurses. The first implication is that patients with leukemia with sleep disturbance are likely to be interested in receiving AA when they feel that it may have beneficial effects for their sleep quality management. In this research, only one participant refused to complete the 4-week research course and dropped out of the study. Attendance at most AA sessions was relatively high. Given the dominance of a TCM culture in China, it seems necessary to employ additional nurses with a TCM background who are capable of providing AA to patients with leukemia suffering from poor sleep quality. A second implication of this study for nurses is that when using AA in a clinical setting, acupuncture point selection and safety are important factors that can affect clinical outcomes. Completing a comprehensive TCM assessment of sleeplessness symptoms will aid nurses in selecting appropriate acupuncture points. In addition, consultation with a TCM nursing specialist from the National TCM Nursing Association for AA intervention is imperative for patients' safety. Developing a protocol with clear guidelines for training and safe use of AA is essential. The third implication of this study is that it is necessary to promote research to establish the scientific validity for the standardization of AA for patients with cancer with poor sleep quality. Continuing to research the effects of AA will enhance research validity concerning the therapeutic use and healing properties of AA.

LIMITATIONS AND RECOMMENDATION FOR FURTHER RESEARCH

Our interpretation of the study findings is limited by the lack of a control group, a small sample size, a short follow-up period, and a lack of blinding of RA nurses and the outcome investigator. Future research should include a suitable control group, a larger sample size, an extended follow-up period, and appropriate concealment and randomization. Moreover, sleep quality was only evaluated via patient self-report PSQI measures. In the future, to enhance the validity of these study results, objective measurement of sleep—possibly via actigraphy and polysomnography—must be used. Furthermore, this research was only conducted at a Hematology hospital clinic. In the future, to enhance the representativeness of the study population, we can choose alternative study locations, such as the community or home.

CONCLUSION

The findings of this study indicate that a 4-week AA intervention significantly improved the sleep quality and reduced sleep medicine usage among patients with leukemia suffering from sleep disturbance. AA is a noninvasive, inexpensive, and non–time-consuming nursing intervention that can be used by nurses along with routine nursing interventions. We recommend

that clinical nurses consider AA as an alternative method of promoting sleep quality in patients with leukemia. Improved sleep quality will improve patients' quality of life and their functional health status, thus directly contributing to a decreased need for pharmacological intervention.

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