Original Article

Effectiveness of Taiwanese traditional herbal diet for pain management in terminal cancer patients

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In addition to modern medicinal therapy, many cancer patients in Taiwan are treated regularly with herbal medicines or prescribed a traditional herbal diet. In this paper, the effect of a Taiwanese traditional herbal diet (TTHD) on pain in terminal cancer patients was investigated. A total of 2,466 patients diagnosed with a variety of cancers were included. The most common patient-reported symptoms included troublesome pain (79.2%), weakness (69.0%), anorexia (46.4%), fever (36.5%), dyspnea (31.1%), and leg edema (30.9%). The 2,466 terminal cancer patients included in the study were randomly divided into three groups. The TTHD group (n=1044; 42.3%) were given the TTHD consisting of analgesic herbs (paeony root: licorice root = 1:1) and a Taiwanese tonic vegetable soup (Lilii bulbus, Nelumbo seed, and Jujube fruit). The remaining patients were divided into a reference group, given the regular hospital diet, (n=909, 36.9%) and a control group, given the Taiwanese tonic vegetable soup without analgesic herbs, (n=513, 20.8%). All patients maintained their assigned diets for one week. A verbal numerical scale was used to assess pain. Results revealed that the patients given TTHD reported enhanced pain relief (p < 0.05) compared to the reference and control groups. We found that TTHD could alleviate the pain among terminal cancer patients thereby supporting the supposition that Eastern and Western medicines can be effectively co-administered to enhance terminal patient's quality of life. Further research is warranted.

Key Words: Taiwanese traditional herbal diet, terminal cancer patients, verbal numerical scale, pain

INTRODUCTION

According to a report issued by the World Health Organization (WHO) in 2000, 10 million people were diagnosed with some form of cancer each year.¹ To date, medical research has been unable to determine the causative factors underlying cancer. As a result, many forms of cancer have no effective therapy, particularly in the later stages of the disease process. Furthermore, 60% of terminal cancer patients suffer from acute pain in the later stages of their disease. Thus, pain management has become one of the top four priorities in the World Health Organization's Integrated Cancer Plan.¹

In Taiwan, cancer has became the leading cause of death since 1982, and it is estimated that approximately 34,000 Taiwanese die of cancer each year.² During the provision of appropriate care, the patients and their concerned family are under a striking amount of stress, affecting both parties physically and spiritually.

Our report in 1998 revealed that fatigue and pain were the two most important factors for cancer patients at Taiwan University Hospital's Ward of Palliative Medicine. A previous paper also highlighted the fact that cancerrelated pain contributes to physiological, psychological, and life quality issues including fatigue, sleeplessness, irritability, anxiety, and anorexia.³ Furthermore, in the case of a terminal cancer patient, management goals are aimed at life enrichment rather than life extension.⁴

Chinese herbal medicines are popular in clinical therapy in Asian countries such as Taiwan, Japan, Korea and China.⁵ Dietary modifications in combination with herbal medicines are commonly employed as complementary medicines and natural nutrition supplements for cancer patients in Taiwan. For example, Shao-Yao-Gan-Cao-Tang, a famous Chinese analgesic prescription, has been prescribed for 2000 years. In Japan and China, Shao-Yao-Gan-Cao-Tang has traditionally been administered to treat general muscle pain or tremors in skeletal muscle. The main pain-removing components are Paeoniae Radix (paeony) and Glycyrrhiza Radix (licorice).⁵ In the field of gynecology, this medicine has been used for the treatment of dysmenorrhea and/or infertility.^{6,7}

Therefore, the purpose of this study was to evaluate the effect of a Taiwanese traditional diet comprised on Shao-Yao-Gan-Cao-Tang on pain, in terminal cancer patients.

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In addition, the secondary objective of this study was to contribute to the integration of Chinese medicine with modern Western medical therapy.

MATERIALS AND METHODS

Subjects

The participants enrolled in this study were terminal cancer patients with pain syndromes who were admitted to the National Taiwan University's Palliative Medicine Ward. Study participants should be capable of oral food intake, and possess stable vital signs. Patients under any analgesics (ex. morphine) treatment were excluded from this study. Both the patient and his or her family had to provide consent for the patient to participate in this study. Data was collected between April 1, 2000 and December 28, 2004. All participants were required to reside at the hospital for a minimum of 10 days. This study was conducted in accordance with the internationally agreed ethical principles for the conduct of medical research.

2,466 terminal cancer patients were randomly divided into three groups for the study. The TTHD group were given the TTHD which consisted of analgesic herbs (paeony root: licorice root = 1:1) and a Taiwanese tonic vegetable soup (Lilii bulbus, Nelumbo seed, and Jujube fruit). The remaining patients were divided into a reference group (given the regular hospital diet) and a control group (given the Taiwanese tonic vegetable soup without analgesic herbs). All patients maintained their assigned diets for one week. Administration of their regular medications was unaltered. A verbal numerical scale was used to assess pain.

Preparation of the Taiwanese dietary intervention

Paeony root (Paeoniae Radix; *Paeonia lactiflora.*) and licorice root (Glycyrrhizae Radix; *Glycyrrhiza uralensis*) for consumption were purchased at a Taipei herbal drug market. The TTHD was devised on Shao-Yao-Gan-Cao-Tang (paeony root: licorice root = 1:1) and a Taiwanese tonic vegetable soup. The soup contained Lilii bulbus, Nelumbo seed and Jujube fruit. The reference group was given a regular hospital diet, the control group was given the Taiwanese tonic vegetable soup and the treatment group was offered the TTHD.

Questionnaire assessment

The questionnaire was designed to collect information regarding patient information, clinical diagnoses, and prevalence of symptoms. Pain was assessed via a verbal and numerical rating scale: comfort without pain (0), minimal pain (25), mild but tolerable pain (50), moderately uncomfortable pain (75), extreme pain (100). The pain rating scale is validated by Prof. Ling-Ling Yang, Taipei Medical University, Taiwan. After the third day of admission to the hospital (day 3), patients were given their respective diets for one week (day 10). Patients completed the questionnaire on day 3 and day 10 and were asked if they experienced pain relief and then rated their pain using the numerical rating scale.

Statistical analysis

The paired *t*-test was used to compare the measure of pain

within each of the three study groups on day 3 and day 10. ANOVA and post-hoc analysis was used to compare between the groups, on the third and tenth days with regard to the degree of pain. The differences were considered to be statistically significant when p < 0.05.

RESULTS

A total of 2,466 subjects were included in this study (Table 1). This included 1,251 male subjects (50.7%) and 1,215 female subjects (49.3%). Most patients (87%) were between 40 and 79 years of age. Only 8.8% of patients were above the age of 80, and 5% were younger than 40. All patients were diagnosed with a terminal cancer, including lung (25.5%), liver (12.4%), colorectal (11.0%), stomach (10.9%), and cervical cancer (5.5%) as illustrated in Table 1.

The most common patient-reported symptoms from the 2,466 subjects are listed in Table 2. Troublesome pain was the most commonly reported symptom, reported by 79.2% (1,953) of the patients. Other frequently reported

 Table 1. Demographic data of the terminal cancer patients (n=2466)

| Variable | n (%) | |
|------------------------|-------------|--|
| Age (years) | | |
| 0 - 9 | 8 (0.36) | |
| 10 - 19 | 18 (0.73) | |
| 20 - 29 | 10 (0.41) | |
| 30 - 39 | 72 (2.91) | |
| 40 - 49 | 396 (16.1) | |
| 50 - 59 | 342 (13.9) | |
| 60 - 69 | 801 (32.5) | |
| 70 - 79 | 603 (24.5) | |
| 80 - 89 | 216 (8.8) | |
| Sex | | |
| Male | 1251 (50.7) | |
| Female | 1215 (49.3) | |
| Primary site of cancer | | |
| Lung | 630 (25.5) | |
| Liver | 306 (12.4) | |
| Colorectal | 271 (11.0) | |
| Stomach | 269 (10.9) | |
| Cervical/Uterine | 135 (5.5) | |
| Kidney | 117 (4.7) | |
| Leukemia | 90 (3.6) | |
| Prostate | 81 (3.3) | |
| ENT | 64 (2.6) | |
| Breast | 62 (2.5) | |
| Pancreas | 54 (2.2) | |
| Esophagus | 45 (1.8) | |
| Bladder | 36 (1.5) | |
| Others | 279 (11.3) | |

| Table 2. Prevalence of symptoms reported in the stud | Ĵу |
|--|----|
| patients (n=2466). | - |

| Primary complaint | n (%) | |
|---------------------|-------------|--|
| Troublesome pain | 1953 (79.2) | |
| Weakness | 1701 (69.0) | |
| Anorexia | 1143 (46.4) | |
| Fever | 900 (36.5) | |
| Dyspnea | 767 (31.1) | |
| Leg edema | 763 (30.9) | |
| Nausea and vomiting | 711 (28.8) | |
| Bleeding | 630 (25.5) | |
| Shortness of breath | 576 (23.4) | |
| Ascites | 540 (21.9) | |

Table 3. Pain assessment via a verbal and numerical rating scale (0-100)

| | Day 3 | Day 10 Mean ± SE | Pain improvement |
|-----------------|--------------------------------|----------------------|------------------|
| | Mean \pm SE | | |
| Reference group | 54.6 ±0.72 | 52.5 ± 0.75 | - 2.1* |
| Control group | 54.7 ± 0.99^{lpha} | 52.0 ± 0.88^{lpha} | - 2.7* |
| TTHD group | $53.0 \pm 0.65^{\alpha,\beta}$ | $50.0\pm0.54^{a,b}$ | - 3.0** |

Comparison within group with paired *t*-test: * p < 0.05, ** p < 0.01. Comparison between groups with ANOVA and post-hoc analysis: "p > 0.05 vs. reference group, "p > 0.05 vs. control group, "p < 0.01 vs. reference group, "p < 0.05 vs. control group."

symptoms included weakness (69.0%, 1,701 patients), anorexia (46.4%, 1,143 patients), fever (36.5%, 900 patients), dyspnea (31.1%, 767 patients), leg edema (30.9%, 763 patients), nausea and vomiting (28.8%, 711 patients), and bleeding (25.5%, 630 patients). The fact that our research revealed that 79.2% of our patients considered pain a primary symptom is indicative of the pervasiveness of this problem.

2466 patients were randomly divided into three groups. Pain questionnaire results from the reference, control, and TTHD groups are presented in Table 3. The reference group patients (receiving only regular palliative care and diet) reported a reductions in pain from 54.6 ± 0.72 on day 3 to 52.5 ± 0.75 on day 10 (p < 0.05). Patients in the control group reported an improvement in pain levels from 54.7 ± 0.99 on day 3 to 52.0 ± 0.88 on day 10. This change was also statistically significant (p < 0.05). The TTHD group reported initial pain levels of 53.0 ± 0.65 on day 3 which decreased to 50.0 ± 0.54 on day 10 (p < 0.001). Patients in the reference group experienced pain amelioration of 2.1. Patients in the control group reported an improvement in pain of 2.7. The difference between these two groups was not significantly different. Patients in the TTHD group reported a 3.0 improvement in pain which was significantly different than the reference and control groups (p < 0.01).

DISCUSSION

The primary goal of palliative therapy in terminal cancer patients is the management of noxious symptoms and discomfort. Secondary goals include meeting the psychological demands of the patients and raising both patient and family understanding of how to safely integrate Chinese medicine into Western treatment regimens to improve the patients' quality of life.⁸

At present, domestic hospices / palliative care facilities and techniques are developing rapidly. The National Taiwan University Hospital's Palliative Ward offers not only specialized medical treatment, but also provides the services of psychologists, art therapists, music therapists, theologians, social workers, and volunteers. These individuals come together as a unit to resolve physiological, psychological, and spiritual problems among the patients residing in the facility. In June 1997, after extensive deliberation, the Palliative Care Unit elected to modify the facility's dietary plans. This change has led to significant improvements in the Palliative Care Unit's services. One such benefit has been improved pain relief in terminal cancer patients who are fed a TTHD.

The research project presented herein included 2,466 patients residing in the National Taiwan University Hos-

pital for a minimum period of 10days between April 1, 2000 to December 28, 2004. Since the most common patient reported symptom was pain (79.2% of patients), Lilii bulbus, Nelumbo seed and Jujube fruit in combination with Shao-Yao-Gan-Cao-Tang was selected as a TTHD.9,10 The Palliative Care Ward unit primarily treats terminal cancer patients on an as-needed basis. When patient pain is controlled, the patient is advised to return to his or her home and embark upon in-home care or make use of Emergency Ward services when needed. This keeps the percentage of patients with pain high.¹¹ Based on previous reports,¹² terminal cancer patient pain could be separated into four categories: (1) pain resulting from the cancer itself, (2) pain resulting from related conditions, (3) pain resulting from therapy-induced side effects such as postoperative pain and chemotherapyinduced oral inflammation, and (4) chronic pain without a direct relationship to cancer, such as headaches and arthritis.

Of the 1,953 patients in this study, it was believed that 90% of them had pain that resulted from other chronic illnesses and not from the cancer. It was believed that the pain experienced by the remainder of the patients was derived from the cancer itself, and in no case did the doctors believe that the pain arose from medical therapy. A possible reason for this is that most of the patients of the Palliative Care Ward would have already undertaken several ineffective treatments prior to moving into this ward. They had undergone treatment for extended periods, and any resulting side effects would have already been played out. It was also clear that the pain of terminal cancer patients deriving from their cancers overrode that arising from any other sources.

Clinical experience reveals that patients suffer from many different kinds of pain, an example is chronic pain in addition to cancer symptom pain. However, patients are often unable to analyze the cause of their pain, and medical professionals are also often unable to make a clear assessment. They are only able to treat all pain as if it arose from the cancer.¹³ Most types of pain respond well when treated with morphine.^{14,15} However, on patients who do not have favorable response, other potential methods should be considered.

The pain of cancer patients can be divided into two types: neuralgic and visceral pain. Since neuralgic pain does not respond very well to morphine, alternate types of analgesics, such as prednisolone,¹⁶ are often required in combination with opioids. Even when pain is of the visceral type, therapeutic methods may vary depending on the different subtypes of visceral pain. For example, pain induced by smooth muscle cramps or intestinal blockage may be treated by hyoscine butylbromide (buscopan).¹⁷⁻¹⁹ This study researched employing the traditional Chinese analgesic materials Paeoniae Radix (peony)²⁰ and Gly-cyrrhiza Radix (licorice).^{21,22} The advantage of using such materials is that they do not have side effects such as gastrointestinal ulcers (often observed in patients prescribed cortisone), or dry mouth and blurry vision caused by buscopan.¹⁷⁻¹⁹

In the assessment of pain, a verbal numerical scale²³⁻²⁶ was applied if the patient was alert and could use language to communicate. When a patient's condition was very poor, he or she was visited on several occasions to ensure an accurate assessment was made. In the event that the patient was unconscious, or if he or she was a child, we employed alternative methods to assess pain levels such as observing the patient facial reactions, anxiety, emotions, shaking, irregular posture, and stiffness of the body. This study only employed assessments arriving from alert patients, and did not incorporate data on patients who were not alert.

This study revealed that patients who were not receiving the soup or TTHD experienced some pain relief from being admitted to the Palliative Care Unit itself. In addition, patients given the soup demonstrated more pain relief than the reference group. Furthermore, patients given the TTHD, which included Shao-Yao-Gan-Cao-Tang, experienced the most improvement in pain. In the latter case, pain improvement achieved significant levels.

The Taiwan National University Hospital's Palliative Care Ward conducts cancer patient pain treatment therapy according to guidelines established by the WHO.³ It uses aggressive application of analgesics to control the pain experienced by cancer patients and has achieved a success rate of about two-thirds. However approximately 21.9% of patients were unable to achieve stable pain control. In the past, the medical community refrained from using morphine. Aside from its side effects, there was also the concern that patient would become physically addicted to opioid analgesics, and develop physiological and psychological dependency. Moreover, morphine has a number of serious side effects such as constipation, nausea and vomiting, respiratory depression, as well as confusion, delusions, and incontinence in some instances.²⁷ In fact, morphine usually controls pain effectively for terminal cancer patients when appropriately applied.

This study has also confirmed that when patients receive palliative care, pain levels of the patients did not rise. However, when patients are on a TTHD, pain levels are significant improved. As a result, we propose that diets including Shao-Yao-Gan-Cao-Tang can potentially reduce patient's reliance on morphine, thereby reducing the incidence of problematic side effects. Based on this study, further research regarding the ability of Eastern medicine to control pain in terminal cancer patients and the integration of Eastern medicine into Western treatment regimens is warranted.

CONCLUSIONS

Cancer patient treatment often requires much time and effort because a low quality of life has a great and pervasive impact on cancer patients and is one of their greatest problems.²⁸⁻³⁴ The pain experienced by patients is an important factor affecting their quality of life.¹⁰ Thus, the pain experienced by patients should receive appropriate attention, and traditional Taiwanese food therapies can be employed to raise their quality of life. For example, Shao-Yao-Gan-Cao-Tang can be employed to complement modern cancer therapies and reduce or eliminate pain, thus improving the quality of life.

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AUTHOR DISCLOSURES

Tsung-Hsiu Wu, Tai-Yuan Chiu, Jaw-Shiun Tsai, Ching-Yu Chen, Lih-Chi Chen and Ling-Ling Yang, no conflicts of interest.

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探討藥膳芍藥甘草湯對癌末病人疼痛的評估

在台灣,除了西醫藥物治療外,許多末期癌症病人亦常使用傳統中草藥或藥 食膳之治療,本研究即探討台灣傳統藥膳對於末期癌症病人疼痛緩解之效 用。本研究共納入2466位病人,臨床主訴症狀分布以疼痛(79.2%)所佔的比例 高,其次為全身倦怠(69.0%)、食慾不振(46.4%)、發燒(36.5%)、呼吸困難 (31.1%)、水腫(30.9%)。試驗者分成空白組(909人)、對照組(513人)及藥膳治 療組(1044人),空白組不給予藥膳,對照組給予米漿,藥膳治療組給予具有 鎮痛之芍藥甘草湯加入米漿中,分別投予一週後,利用設計問卷調查以口述 數字評分法(Verbal Numerical Scale)評估,研究結果顯示以芍藥甘草藥膳調養 病人疼痛症狀有明顯改善(p<0.01),傳統中國食療期能幫助病人支持其精神生 活,改善生活品質,相關臨床實證值得進一步評估探討。

關鍵字:芍藥甘草湯、癌末病人、安寧照顧、疼痛。