

Is there a role for acupuncture in the symptom management of patients receiving palliative care for cancer? A pilot study of 20 patients comparing acupuncture with nurse-led supportive care

Jan T W Lim,¹ Erin T Wong,² Steven K H Aung³

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¹Division of Radiation Oncology, Department of Surgery, University of British Columbia, Vancouver, British Columbia, Canada

²Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada

³Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Alberta, Canada

Correspondence to

Dr Jan T W Lim, 2410 Lee Avenue, Victoria V8R 6V5, British Columbia, Canada; jlim@bccancer.bc.ca

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Abstract

Purpose A pilot study to document changes in symptoms after acupuncture or nurse-led supportive care in patients with incurable cancer.

Methods Patients receiving palliative care with estimated survival of at least 3 months were screened with the Edmonton Symptom Assessment System (ESAS). Patients (n=20) with significant symptoms were randomised to receive weekly acupuncture or nurse-led supportive care for 4 weeks. ESAS scores were obtained before and after each treatment, and weekly for 6 weeks after treatment by telephone.

Results 42 of 170 patients screened were eligible. 20 gave consent for recruitment. The compliance rate was 90% for acupuncture and 80% for nurse-led supportive care. Total symptom scores were reduced by an average of 22% after each acupuncture visit and by 14% after each supportive care visit. Compared with baseline, ESAS scores at the end of the follow-up period were reduced by 19% for the acupuncture arm and 26% for nurse-led supportive care.

Conclusion Patients appear to benefit from incorporating acupuncture in the treatment of advanced incurable cancer. Acupuncture was well tolerated with no significant or unexpected side effects. Acupuncture had an immediate effect on all symptoms, whereas nurse-led supportive care had a larger impact 6 weeks after the final session. Both interventions appear helpful to this population and warrant further study.

INTRODUCTION

Patients with advanced cancer experience multiple symptoms that reduce their quality of life (QOL). There have been significant improvements in the management of pain, nausea and constipation, but other common symptoms such as fatigue, anxiety, depression and a lack of well-being are not always readily addressed by conventional medical therapies. As patients with cancer present with numerous symptoms, it can be advantageous to address all of these globally, instead of focusing only on individual symptoms

that respond well to conventional therapy. Attempts at controlling individual symptoms can sometimes give rise to iatrogenic effects, which create new symptoms or worsen the existing symptoms. A well-known example of this is constipation from opiate analgesics for pain control. Successful treatment from the care giver's perspective is often scored against each symptom that is being treated. From the patient's point of view, it is the interplay of the whole treatment package that succeeds or fails in improving his QOL.

In an attempt to treat all of the patient's symptoms globally, research into the use of complementary and alternative medicine has been conducted to determine the utility of these treatments in addressing the unmet needs of many patients with cancer.¹ Sagar and Cassileth² recommend integrating complementary therapies to help manage pain, nausea, fatigue, anxiety and other symptoms in patients with cancer. There is preliminary evidence that acupuncture is successful at improving many cancer- and treatment-associated symptoms.^{3,4}

Acupuncture involves the insertion of thin solid metallic needles into specific points on a person's body to elicit specific reactions.⁵ These effects have been discovered empirically, and the theoretical basis is the flow of vital energy (Qi), which is regarded as the life-force. Acupuncture needles can be connected to low-voltage oscillating currents to mimic the traditional manual stimulation of needles for the desired effect.⁶

Support for the use of acupuncture in the palliative setting has come from several publications. Alimi *et al*⁷ reported that the use of acupuncture in patients with persistent pain despite stable analgesic treatment resulted in a significant reduction in pain sensation. This included several patients with neuropathic pain that had been refractory to conventional treatment. Wong and Sagar⁸ found similar results in a pilot study of acupuncture for the treatment of chemotherapy-induced neuropathy. Vickers *et al*⁹ examined the use of acupuncture for the treatment of post-chemotherapy fatigue and,

based on their positive (though not statistically significant) results, suggested that there is sufficient evidence to merit further study. It has also been reported that acupuncture is effective in reducing nausea and vomiting associated with chemotherapy.^{10 11}

In recent years, randomised controlled trials (RCTs) have been used to test the efficacy of acupuncture via comparison with various forms of sham acupuncture. Opinion on the use of sham acupuncture in RCTs remains mixed, and its effects are often indistinguishable from acupuncture.^{12–14} Recent studies have reported the use of novel techniques that may prevent patients^{15 16} and practitioners¹⁷ from distinguishing between acupuncture treatment and placebo. However, there is evidence that sham acupuncture techniques can induce physiological responses similar to those of true acupuncture¹⁸ and therefore cannot be considered a reliable placebo.

Nurse-led supportive care has been shown to be helpful in ameliorating symptoms in terminal care. Solà *et al*¹⁹ have described the potential benefit of nurse intervention in patient's well-being. Uitterhoeve *et al*²⁰ reviewed psychosocial interventions, including nursing interventions, and reported a potential positive effect.

Given the potential to improve symptoms and QOL,²¹ acupuncture was investigated to assess its effectiveness in patients with symptoms of advanced cancer. Because it was unknown if there is sufficient interest among patients and referring physicians, a pilot study of 24 patients was planned to determine the interest, feasibility and acceptance of an unconventional treatment modality.

As any improvement to patients receiving acupuncture can be attributed to medical empathy, this treatment will be compared with the nurse-led supportive care.

Aims

The specific aims of this study were to document the change in symptoms after acupuncture or nurse-led supportive care and to determine the feasibility of carrying out a randomised study in acupuncture for patients with advanced incurable cancer.

PATIENTS AND METHODS

Sample description

Patients recruited into this study were registered with the BC Cancer Agency at the Vancouver Island Centre in Victoria. These patients attended the Pain and Symptom Clinic for palliative management of cancer and treatment-related symptoms. The commonly experienced symptoms of pain, tiredness, nausea, depression, anxiety, drowsiness, anorexia, lack of well-being and shortness of breath were investigated. During the study, recruited patients were managed in the usual way and continued to receive standard medical advice and treatment for their symptoms.

The Edmonton Symptom Assessment System (ESAS) graph (online appendix 1) is a validated tool that is used to measure any changes in the symptoms experienced by patients before and after the intervention.²² This evaluation is based on the patients' subjective level of symptom

severity as circled on a numerical scale of 0–10, where 0 represents no symptoms and 10 represents the worst possible severity of the symptom. To avoid bias, patients scored their own symptoms without any help. The acupuncturist and palliative care nurse were unaware of the ESAS scores obtained at each visit.

To screen for potential study participants, the attending physician invited patients who were estimated to survive at least 3 months to complete an ESAS form. Patients were eligible for the study if they scored at least 5 out of 10 in one or more of the following symptoms: tiredness, drowsiness, anxiety and lack of well-being. These symptoms are often not easily managed by conventional means. Patients were ineligible if they had acupuncture within 3 months of recruitment to the study or if they were known to have impaired clotting of blood.

Eligible patients who wished to participate were made aware of the side effects of acupuncture, gave written consent and were randomised to either acupuncture or nurse-led supportive care once a week for 4 weeks. In the Memorial Sloan-Kettering study of acupuncture for post-chemotherapy fatigue, there was no important difference in improvement following once-weekly and twice-weekly treatments for 4 weeks.⁹ Patients in the control arm received supportive care for a similar length of time (20–30 min) from a palliative care nurse on a weekly basis for 4 weeks. Patients began treatment within 3 weeks of randomisation. Patients who missed a treatment were rescheduled to attend the following week. As this was a pilot study and it was known that the limited sample size would prevent significant comparison between the arms, no attempt was made to match groups for variables such as symptoms and medications. Patients in both groups were given the freedom to adjust their medications according to medical advice.

After the 4-weekly interventions, the study coordinator conducted a follow-up telephone interview on a weekly basis for 6 weeks after the final intervention. Thus, each study patient was required to attend four sessions and complete six telephone follow-ups over a 3-month period.

Acupuncture

Traditional Chinese Medical acupuncture was performed by the principle investigator (PI), a radiation oncologist and a certified medical acupuncturist. The PI was instructed by Steven K H Aung and certified by the University of Alberta and had more than 6 years of acupuncture experience during the study.²³

Sterile, disposable, single-use acupuncture needles (ITO Addiquip Number 5, 0.25×50 mm) were inserted at the 15–30 acupuncture points per subject determined to be most effective for that patient on the day of treatment. Acupuncture points were chosen based on the symptoms experienced (see table 1 for possible selection). Needles were inserted to a depth of 5–15 mm and *de qi* (sensation of heaviness and fullness) responses were sought.

The acupuncture needles were connected to an electrical stimulator (ITO Electroacupuncture Unit ES160), which took the place of traditional manual stimulation

of needles for the desired effect. Alternating patterns of stimulation have been shown to be most effective for the relief of pain.²⁴ A 0.3 ms duration, 4-Hz alternating current

was delivered. The needles were stimulated for 20 min and then removed. Voltage was set at a level just below the pain threshold of each patient.

Table 1 Acupuncture points

Point(s)	Pain	Tiredness	Nausea	Depression	Anxiety	Drowsiness	Loss of appetite	Lack of well-being	Shortness of breath
Lung									
1									✓
5									✓
9								✓	
Large intestine									
4	✓								
Stomach									
21							✓		
34			✓						
36		✓					✓		
41	✓		✓	✓			✓		
43	✓								
Spleen									
6		✓							
8		✓							
9		✓							
10				✓				✓	
Heart									
7					✓				
Small intestine									
18	✓								
Bladder									
14					✓				
15					✓				
17								✓	
18				✓					
60	✓								
Kidney									
3	✓	✓							
6	✓					✓			
7	✓								
10	✓	✓							
Pericardium									
6	✓		✓	✓	✓		✓		
Gallbladder									
39								✓	
Liver									
3				✓				✓	
8								✓	
14				✓					
Governing vessel									
4	✓							✓	
12					✓				
13					✓				
20	✓				✓	✓			
Conception vessel									
4								✓	
6		✓	✓					✓	
12			✓				✓	✓	
17				✓				✓	✓
Triple burner									
5				✓	✓				
Extra points on the head and neck						✓			
Ear shenmen	✓				✓				
Ear subcortex	✓								
Ear sympathetic	✓								
Ear liver			✓						

*Based on Aung and Chen.²³

Although the amount of time spent with the patient was similar, the acupuncturist did not provide counselling or support to the patient beyond that involved in delivering acupuncture.

Nurse-led supportive care

Patients met for 20–30 min with an experienced palliative care nurse weekly for 4 weeks. This amount of contact was comparable with the time spent in the acupuncture arm.

The nurse asked the patients to elaborate on their most troubling symptoms, discussed the use of medications and non-medicinal therapies (eg, relaxation therapy, counselling from a professional counsellor, exercise or judicious rest) and sought the patient's interpretation of the causes of the symptoms and how they could be ameliorated. The nurse addressed issues such as improving the scheduling and dosing of medications, suggesting alternatives to drug therapy (eg, different foods for managing constipation), and checking the appropriateness of drugs available to the patient, particularly drugs used on an 'as required' basis (including over-the-counter medication). The nurse was able to convey concerns about specific symptoms back to the relevant palliative care team.

She also suggested useful strategies for coping with daily activities, offered emotional support and was seen by the patient as an advocate.

Instrument/study measures

Prior to and immediately after each of the 4-weekly interventions, patients filled out an ESAS form. The acupuncturist and palliative care nurse were unaware of the ESAS scores obtained at each visit. Scores were also obtained via weekly telephone interview for 6 weeks following completion of each intervention.

Primary end points

For each symptom, changes in ESAS score were averaged for all the patients and rounded to the nearest 0.25 step for each arm of the study. The mean change in scores after each intervention session and at subsequent follow-ups was analysed.

All the nine symptom scores reported were summed up to obtain a total ESAS score for each patient. The average total ESAS score for both the acupuncture and nurse-led supportive care arms was calculated before and after each visit and for each week of follow-up.

Secondary end points

Proportions of patients eligible, as well as those who consented to be recruited, were determined. The study also determined the degree of compliance to completing all four of the intervention sessions in both groups of patients.

Planned sample size

For this feasibility study, it was planned to recruit 12 patients in each arm, for a total of 24 patients. This was considered adequate to determine the level of interest, degree of compliance and tolerability of acupuncture

for patients with advanced incurable cancer. These data will be used to support a larger study that is powered to detect the difference between the modalities. Because of the small sample size, only descriptive statistics were used for comparison of the ESAS scores.

Randomisation

A computer-generated sequence of random numbers was used to assign patients to acupuncture or supportive care. These designations were sealed in serially numbered envelopes before the study was open for registration. When an eligible patient was identified, an envelope was opened to assign the recruited patient to acupuncture or supportive care.

Ethics approval

The study has been approved by the University of British Columbia Office of Research Services Ethics Committee.

RESULTS

Recruitment and sample characteristics

One hundred seventy patients were screened for eligibility between April 2006 and March 2008 from approximately 80 Pain and Symptom Clinics. Twenty-five per cent (42/170) of patients screened were eligible. Forty-eight per cent (20/42) of eligible patients consented for recruitment.

The study was closed after 2 years, with 20 patients recruited out of the planned 24. Two patients withdrew, leaving 18 in total for participation in the study (see table 2 for patient characteristics).

Acupuncture

One patient withdrew after two treatments due to a large number of medical appointments, leaving nine patients

Table 2 Patient characteristics

Characteristics	Acupuncture	Nurse-led supportive care
	Frequency	
Age	55	64.9
(mean (SD; range))	(11.1; 31–72)	(8.7; 53–81)
Weight	74.3	64.3
(mean (SD; range))	(18.5; 51.7–101.5)	(14.7; 34.0–85.3)
Gender		
Male	2	1
Female	8	7
Tumour site		
Breast	2	2
Rectum	2	0
Endometrium	1	1
Cervix	1	
Oropharynx	0	1
Bladder	0	1
Leukaemia	0	1
Kidney	1	0
Myeloma	1	0
Lung	1	0
Caecum	1	0
Oesophagus	0	1

who completed all four treatments. Acupuncture was well tolerated with only two cases reporting minor side effects. One patient experienced right-leg stiffness after the first treatment, which cleared after a day. Another reported a 'falling asleep' sensation in the left arm and leg. This patient was assessed by his physician the same day and sent for a CT brain scan that did not show any metastasis or stroke; the symptom resolved a day later. Treatment was not interrupted aside from the one patient who withdrew. There were some instances of missed follow-ups because of poor health and hospitalisation.

Averaged changes in ESAS scores for the nine acupuncture patients are described in table 3. After each acupuncture session, scores were reduced by 1.0–2.0 for pain, tiredness, lack of well-being and shortness of breath. There was a smaller reduction of 0.25–0.75 for nausea, depression, anxiety, drowsiness and loss of appetite. Patients generally had a higher score for drowsiness when they returned for subsequent treatment, but this was reduced after each acupuncture session.

At 6 weeks after acupuncture, the score was reduced by 2.75 for shortness of breath and 1–1.5 for tiredness, depression, anxiety, drowsiness and a lack of well-being. Pain, nausea and loss of appetite improved during acupuncture, but the benefit was transient, and scores were 0.25–1.5 higher at 6 weeks.

Nurse-led supportive care

After randomisation, two patients withdrew, leaving a total of eight who received supportive care. Supportive care was well tolerated, and there was no interruption of these sessions. There were some instances of missed follow-ups because of poor health and hospitalisation. One patient died unexpectedly of a stroke before telephone follow-up.

Averaged changes in ESAS scores for the eight supportive care patients are described in table 3. After each supportive care session, there was a small reduction in score of 0.25–0.75 for pain, anxiety, drowsiness, loss of appetite

and shortness of breath. There was no immediate benefit for tiredness, nausea or depression. Patients with anxiety and shortness of breath had the largest improvement.

At 6 weeks after supportive care, the score was reduced by 2.0–2.5 for nausea, depression, anxiety, drowsiness and a lack of well-being. Pain, tiredness and loss of appetite were reduced by 1.25–1.5.

Total ESAS score

The change in the averaged total of all nine symptom scores is shown in figure 1. Total symptom scores were reduced by an average of 22% after each acupuncture visit and by 14% after each supportive care visit. During the 6 weeks of follow-up, mean total scores for nurse-led supportive care continued to decline, whereas acupuncture scores increased but declined again by week 6. Compared with baseline, ESAS scores at the end of the follow-up period were reduced by 19% for the acupuncture arm and 26% for nurse-led supportive care.

DISCUSSION

Only 25% of patients screened were eligible for participation, as many of the patients were not expected to survive 3 months. Only 48% of eligible patients were recruited because many of the patients did not want to be randomised to the non-acupuncture arm of the study. The study was closed after 2 years with 20 participants. The target of 24 patients was not achieved due to poor recruitment (20/170 or 12%) and competing trials being started in palliative care.

Results from this pilot study confirm the feasibility of acupuncture as a treatment for symptom reduction in palliative cancer care. ESAS scores were lower after each treatment, with the largest reductions seen for pain and tiredness. At 6 weeks after acupuncture, all of the symptoms remained improved except for pain, nausea and loss of appetite. This observation is not surprising as it is known that many acupuncture schedules for chronic con-

Table 3 Symptom score changes following acupuncture and nurse-led supportive care

Symptoms	Acupuncture			Nurse-led supportive care		
	Baseline ESAS score	Mean change in ESAS score*		Baseline ESAS score	Mean change in ESAS score*	
	Mean (range)	Per session [†]	At 6 weeks [‡]	Mean (range)	Per session [†]	At 6 weeks [‡]
Pain	5 (1–8)	–1.5	+0.5	5 (0–7)	–0.25	–1.25
Tiredness	5.5 (2–10)	–2.0	–1.25	6 (4–8)	0	–1.5
Nausea	1.8 (0–10)	–0.75	+0.25	2.75 (0–7)	0	–2.5
Depression	4.6 (0–8)	–0.5	–1.25	3.1 (0–7)	0	–2.0
Anxiety	4.4 (1–7)	–0.5	–1.25	4 (1–7)	–0.75	–2.0
Drowsiness	5.1 (1–9)	–0.5	–1.25	4.1 (0–8)	–0.75	–2.0
Loss of appetite	4.4 (0–10)	–0.25	+1.5	4 (0–7)	–0.25	–1.5
Lack of well-being	5.7 (3–8)	–1.0	–1.5	4.4 (0–8)	–0.25	–2.25
Shortness of breath	3 (0–9)	–1.0	–2.75	3.1 (0–7)	–0.5	–0.25

*All changes in ESAS score were calculated by averaging for all patients and rounding to the nearest 0.25.

[†]Mean change per session is the averaged change in score after each of the four sessions. This describes the immediate effect of the sessions.

[‡]Mean change at 6 weeks is the change in score from baseline to the last week of follow-up. This describes the longer-term effect of the sessions. ESAS, Edmonton Symptom Assessment System.

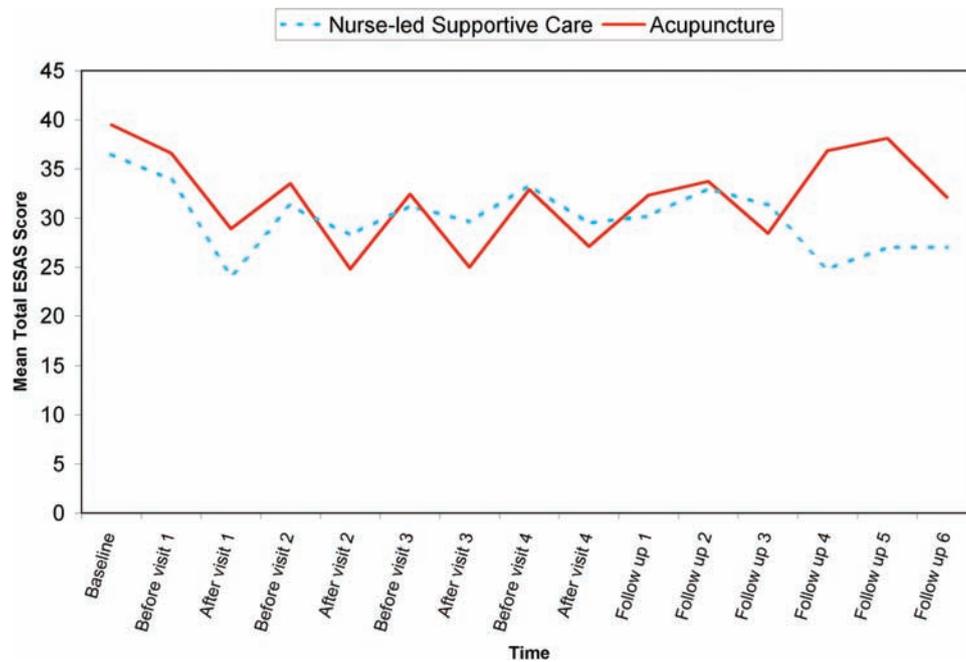


Figure 1 Time trend in total ESAS symptom scores for acupuncture (n=10) and nurse-led supportive care (n=8). Mean scores are shown before and after the 4-weekly visits and for 6 weeks of follow-up. ESAS, Edmonton Symptom Assessment System.

ditions involve weekly treatments for 4–6 weeks, followed by maintenance treatments every 2–4 weeks. It is possible that having acupuncture patients return for maintenance sessions could help to prolong the improvements seen in this population, but this still needs to be determined. In fact, the results are surprisingly durable when one considers the progressive nature of the underlying disease. In a recent study of 808 patients with advanced cancer, Zeng *et al*²⁵ found that the scores for all nine ESAS symptoms deteriorated significantly as patients neared the end of life. Considering the expected deterioration of symptoms in patients with incurable cancer, the symptomatic benefit may exceed the observed 19% reduction in total ESAS score after the course of acupuncture treatment.

The study also confirms that nurse-led supportive care can improve symptoms in these patients. Except for tiredness, nausea and depression, the ESAS scores were lower after each session. At 6 weeks, all nine symptoms were improved. These improvements can likely be attributed to increased attention and quality feedback being provided from the palliative care nurse to the medical team who were able to initiate positive changes in medication and other supportive measures.

For future large-scale trials, randomisation would be carried out to show that the benefit from acupuncture is more than that achievable purely from medical empathy. This could not be shown from this pilot study alone. Overall it appears that acupuncture may provide more immediate symptom improvements, whereas nurse-led supportive care may be effective in ameliorating symptoms over longer periods of time, possibly from learned strategies of coping, and increased home care mechanisms. However, the small sample size of this pilot study

prevents significant comparison of the two arms. Further study involving larger cohorts will be needed to confirm these conclusions.

Conclusions

This study suggests that patients can benefit from incorporating acupuncture to help with symptoms of advanced incurable cancer. The treatment was well tolerated with no significant or unexpected side effects and patient compliance was good (90% for acupuncture, 80% for nurse-led support).

All nine symptoms were improved immediately after acupuncture with improvements continuing in six of these symptoms after 6 weeks. Six symptom scores improved immediately following nurse-led supportive care visits, with all nine symptoms showing improvement after 6 weeks. This pilot study confirms the feasibility of both acupuncture and nurse-led support for this patient population and justifies the need for future RCTs to confirm their efficacy in palliative cancer care. The success of acupuncture in improving multiple symptoms simultaneously makes it an attractive treatment option for use along with current conventional therapies.

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