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Recent Advances in Oncology Acupuncture and Safety Considerations in Practice

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Opinion statement

Oncology acupuncture is a new and emerging field of research. Recent advances from published clinical trials have added evidence to support the use of acupuncture for symptom management in cancer patients. Recent new developments include (1) pain and dysfunction after neck dissection; (2) radiation-induced xerostomia in head and neck cancer; (3) aromatase inhibitor-associated arthralgia in breast cancer; (4) hot flashes in breast cancer and prostate cancer; and (5) chemotherapy-induced neutropenia in ovarian cancer. Some interventions are becoming a non-pharmaceutical option for cancer patients, while others still require further validation and confirmation. Meanwhile, owing to the rapid development of the field and increased demands from cancer patients, safety issues concerning oncology acupuncture practice have become imperative. Patients with cancer may be at higher risk developing adverse reactions from acupuncture. Practical strategies for enhancing safety measures are discussed and recommended.

The emergence of new research data is expanding the use of acupuncture for symptom management in cancer. Since Sarga's review article in *Current Treatment Options in Oncology* in 2008 [1•], several newly published scientifically rigorous clinical trials of acupuncture have added new evidence of its effectiveness.

Neck and shoulder pain after neck dissection

In a prospective, open label, randomized controlled trial (RCT), Pfister *et al.* demonstrated that acupuncture may benefit head and neck cancer patients, who were suffering from moderate or severe pain after neck dissection and radiation therapy [2•]. Seventy patients were randomized to receive acupuncture plus usual care arm vs usual care. Acupuncture was given once a week for 4 weeks. At the end of 6 weeks of the study, the acupuncture arm was found significantly superior to control for all outcome measures including the Constant-Murley Scale (95% CI, 3.0 to 19.3; $P = 0.008$), Xerostomia Inventory (XI) scores (95% CI, -1.0 to -10.7; $P = 0.02$), and Numerical Rating Scale scores of pain (95% CI, -0.8 to -2.7; $P < 0.001$). It was noteworthy that the median time from surgery in the acupuncture group was 39 months (3.25 years), indicating that patients who had chronic pain could still benefit from the acupuncture intervention.

Radiation-induced xerostomia in head and neck cancer

Since Blom's report in 1992 [3], acupuncture has been repeatedly showing positive results for radiation-induced xerostomia. Garcia *et al.* reported their study results, in a single arm, pilot study ($N = 19$), as follows. Patients with squamous cell carcinoma of head and neck treated with a mean dose of 68.2 Gy radiation received acupuncture [4•]. The median time

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from completion of the radiation to the beginning of acupuncture was 28.2 months (2.35 years). Acupuncture treatment was given twice a week for four consecutive weeks. At week 8, 1 month after completion of the acupuncture treatment, the partial response rate (defined as XI score difference ≥ 6 points from baseline) was 55.56%. In addition, XI, Patient Benefit Questionnaire (PBQ), and the Functional Assessment of Cancer Therapy-Head and Neck (FACT-H&N) quality of life measurement were all significantly better on weeks 4 and 8 than at baseline (XI: $P = 0.0004$ and 0.0001 ; PBQ: $P = 0.0004$, and 0.0011 ; FACT-H&N total score: $P = 0.04$ and 0.03 , respectively).

Aromatase inhibitor (AI) associated arthralgia in breast cancer

Crew *et al.* reported on a randomized sham-controlled acupuncture trial involving 43 women with early-stage breast cancer complaining of musculoskeletal pain associated with the use of AI, anastrozole, and letrozole [5•]. The mean worst pain score measured by Brief Pain Inventory-Short Form (BPI-SF) was 6.7 out of 10 scale at baseline. After 6 weeks, i.e., 12 acupuncture sessions, the mean worst pain score was 3.0 in the acupuncture arm, compared to 5.5 in the sham group ($P = 0.002$).

Vasomotor symptoms in breast cancer and prostate cancer

Vasomotor symptoms are common side effects of hormone therapy in women with breast cancer and in men with prostate cancer. Fifty women with hormone-receptor-positive breast cancer were randomized into an acupuncture vs Venlafaxine trial [6•]. Patients in the study received acupuncture twice a week for the first 4 weeks, thereafter once a week for the remaining 8 weeks. The authors found that both groups showed significant decreases in hot flashes (50%), symptoms of depression, and other quality of life related symptoms from pre- to post-treatment. Long-term follow-up at 3-, 6-, 9-, and 12 months showed similar results between the two groups. The authors concluded that acupuncture appears to be equivalent to the drug therapy in these patients but with less side effects compared to those on Venlafaxine.

In prostate cancer, Beer and Ashamalla independently reported on two open label, single arm, phase II trials ($N = 25$ and 14 , respectively) [7•,8•]. In both studies, prostate cancer patients treated with androgen deprivation therapy, with elevated mean hot flash scores, one at 16.2, and the other 28.31, were recruited. Manual acupuncture was given twice a week for the first 4 weeks, and once a week for the remaining 6 weeks in Beer's trial, while electroacupuncture was given for twice a week for 4 weeks in Ashamalla's trial. Response was defined as a $>50\%$ reduction in hot flashes. The response rates were 41% at week 4 and 55% overall in Beer's trial, and 86% at the week 2, 100% at week 6, and 91% at 8 months in Ashamalla's trial. Both those authors indicated that those changes were clinically significant and future RCTs were warranted.

Chemotherapy-induced neutropenia in patients with ovarian cancer

We conducted a pilot randomized sham-controlled trial of acupuncture for chemotherapy-induced neutropenia in patients with ovarian cancer [9•]. Twenty-one newly diagnosed and recurrent ovarian cancer patients received manual and electro-acupuncture stimulation vs sham acupuncture, 2–3 times per week for a total of 10 sessions, during one cycle of myelosuppressive chemotherapy. At the end of 10 sessions, which was the first day of the third cycle of chemotherapy, the median leukocyte value was significantly higher in the acupuncture arm compared with the sham arm (8,600 cell/ μL vs 4,400 cell/ μL , $P = 0.046$), suggesting a potential myeloprotective effect of acupuncture.

Additional acupuncture studies in the past year include (1) the first pilot acupuncture study in a palliative care setting demonstrating an improved quality of life in advanced cancer patients [10]; (2) a RCT-measured acupuncture treatment for postoperative gastroparesis syndrome after abdominal surgery in patients with primary liver cancer [11]; (3) a case series in which 16 cancer patients experienced completed or satisfactory remission of persistent hiccups [12]; and (4) a case series report on acupuncture for dysphagia after chemoradiation in head and neck cancer patients, demonstrating a positive outcome, i.e., a relatively shorter duration needed for percutaneous endoscopic gastrostomy (PEG) tube [13].

Safety considerations in oncology acupuncture practice

With an increasing number of positive evidence-based acupuncture trials, more cancer patients may seek acupuncture treatment. While closely monitored clinical trials often report low incidences of adverse events of acupuncture, many physicians remain concerned about its safety.

Over the last 10 years, there have been several large prospective and long-term retrospective studies that have demonstrated an excellent safety profile of acupuncture. The rate of minor adverse events was estimated to be 14 per 10,000 sessions in one study [14], while serious adverse events estimated to be 0.05 per 10,000 treatments, and 0.55 per 10,000 individual patients [15]. The common complications of acupuncture are infections, blood-borne diseases, internal organ, and tissue injury.

However, the reported low incidence of side effects does not necessarily translate into a safe practice for all oncology patients, because of several factors. First, most of the above mentioned studies were conducted in developed countries, where acupuncture practice widely follows the Clean Needle Technique (using disposable needles, hand washing, and immediately discarding each used needle into a sharps container). Second, the term “acupuncture” is heterogeneous, and its definition varies in different regions of the world. The current investigation of acupuncture has primarily focused on the procedure of skin penetration by thin, solid, metallic needles. The safety profiles of other acupuncture variations, such as direct and indirect moxibustion, imbedded needles, ear seed imbedding, and acupuncture point injection with or without medications, which have been reportedly used in cancer patients, have yet to be established. Third, in an institutional acupuncture practice, such as a cancer center, clinicians usually have access to electronic medical records, nursing support, and consultation from the primary oncologists of the patient being treated. These supports construct a safety net for the patients, while a community acupuncture practice often lacks such support. Fourth, owing to the rapid development of this field, specialized oncology acupuncturists are still a minority. In addition to comprehensive training in acupuncture and Eastern Asian Medicine, an oncology acupuncturist is required to possess a solid knowledge and clinical skills in allopathic medicine; with experience in treating a variety of oncology cases, and the ability to interact with an oncology multidisciplinary team.

Patients with cancer may be at a higher risk for developing adverse effects due to their compromised immune function, chemotherapy-induced pancytopenia, radiation effects, tumor progression, and metastatic disease. They are more susceptible to infections and hemorrhage. Other potential acupuncture-related risks include needling tumor or metastatic sites, limbs with lymphedema, and hematomas. We generally discourage our patients seeking acupuncture treatment in the community when they present one of the following conditions: (1) during the courses of chemotherapy/radiation therapy; (2) severely impaired hematological profiles such as neutropenia or thrombocytopenia; (3) advanced disease with

major co-morbidities; (4) pain caused by multiple bone metastasis; and (5) brain metastasis with central nervous system involvement.

Specific safety concerns related to oncology acupuncture is an area of investigation. In those with thrombocytopenia, Ladas *et al.* retrospectively investigated medical records of 32 pediatric cancer patients (median age 15.7), who received acupuncture for cancer or during stem cell transplantation [16]. No bleeding side effects were observed and recorded even in patients with severe thrombocytopenia ($\leq 20,000/\mu\text{L}$). Apparently, the excellent safety record was collectively achieved when the following requirements were all met: using a specific type of thin needle, mild manual stimulation administered at a shallow depth, by an experienced acupuncturist at an academic cancer center with an established acupuncture program.

Therefore, establishing an eligibility guideline for cancer patients before receiving acupuncture would add another layer of safety. In the last 10 years, we have used the following guidelines to determine patient eligibility for acupuncture treatment at our institution. Cancer patients would NOT be recommended for acupuncture if they have one of the following conditions: (a) absolute neutrophil count (ANC) less than $500/\mu\text{L}$; (b) platelet count less than $25,000/\mu\text{L}$; (c) altered mental state; (d) clinically significant cardiac arrhythmias; and (e) other unstable medical conditions (case-by-case consideration). Before the first visit, an approval is required from the primary oncologist based upon these guidelines.

Conclusions

Efficacy and safety of oncology acupuncture should be simultaneously evaluated. Although the evidence generated from recent oncology acupuncture clinical trials are still not ready for primetime to change practice in general, the quality and design of clinical trials of acupuncture have significantly improved. When simultaneously assessing benefit and risk ratio of present data, acupuncture is becoming one of the non-pharmaceutical treatment options for symptom management in cancer patients. Nevertheless, studies with weak data are still prevalent.

Protecting cancer patients from unnecessary harm is the basic principle of oncology acupuncture practice. There are practice guidelines for patients with cancer [17•]. Safety measures for oncology acupuncture include training well-qualified oncology acupuncturists as a subspecialty, encouraging standardized clinical practice, improving, and disseminating practice guidelines. Oncology acupuncture can be a safe practice only if associated risks are recognized and well managed. The field is moving forward.

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