An Evaluation of Electroacupuncture for Control of Myeloablative Chemotherapy-Induced Emesis: A Randomized Controlled Trial

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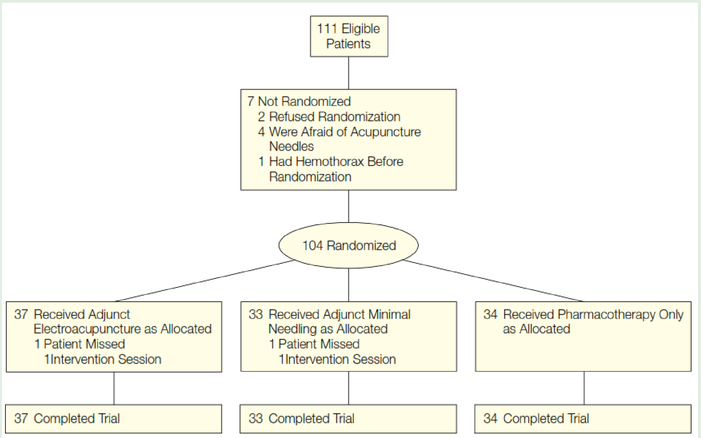
Background

For the Chinese medical claims of efficacy to win acceptance within western scientific circles, more rigorous research are needed. Implementation of Cochrane Collaboration's Tool[1] and the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA)[2] can improve the quality of TCM trials. We selected a clinical trial[3]published in JAMA (*Figure 1*) and evaluated this study using the aforementioned criteria.

Figure 1: Trial Profile



The objective of this clinical trial is to compare effectiveness of electroacupuncture vs other treatment methods (minimal needling, mock electrical stimulation, or antiemetic medications alone) in controlling emesis among breast cancer patients undergoing a highly emetogenic chemotherapy regimen. This three-arm, parallel-group, randomized controlled trial was conducted between March 1996 and December

Objective

- Review a three-arm, parallel-group, randomized controlled trial to explore applicability of Acupuncture & Oriental Medicine (AOM) in integrative medicine.
- Provide recommendations for future TCM trials.

Methods

- This evaluation used Cochrane Collaboration's Tool to assess the risk of bias and the STRICTA guidelines to assess the quality of reporting of this study.
- Cochrane's bias classification scheme includes selection bias, performance bias, detection bias, attrition bias, and reporting bias (*Table 1*)
- STRICTA's checklist sets out reporting guidelines for acupuncture rationale, the details of needling, the treatment regimen, other components of treatment, the practitioner background,

Table 1: Trial Evaluation based on Cochrane Collaboration's Tool

Type of Bias	Details	Evaluation
1. Selection bias	1a) Sequence generation. 1b) Allocation concealment.	The patients were randomly assigned without stratification. Serially numbered, sealed, opaque envelopes were used to indicate assignment.
2. Performance bias	2a) Blinding of participants and personnel. 2b) Other potential threats to validity.	While masking the acupuncturists to the interventions is impossible, researchers were able to achieve adequate masking of the patients.
3. Detection bias	3a) Blinding of outcome assessment. 3b) Other potential threats to validity.	The nurse's recording was used to measure emesis. Nurses were not informed of the treatment group.
4. Attrition bias	4) Incomplete outcome data	All patients completed the trial and there were no losses to follow up, minimal deviations from assigned treatment regimens, and no major adverse events.
5. Reporting bias	5) Selective outcome reporting	This trial reports similar outcome measures when compared to other trials.

Table 2: Trial Evaluation based on STRICTA Checklist

Checklist Items	Details	Evaluation
1. Acupuncture rationale	1a) Style of acupuncture 1b) Reasoning for treatment 1c) Extent to which treatment was varied	The protocol was based on prior literature, acupuncture textbooks, suggestions from consultant practitioners. Electrical frequency was delivered over 2 to 10 Hz, 0.5 to 0.7 milliseconds duration pulse width for 20 minutes.
2. Details of needling	2a) Number of needle insertions per subject per session 2b) Names of points used 2c) Depth of insertion 2d) Response sought 2e) Needle stimulation 2f) Needle retention time 2g) Needle type	36-guage disposable stainless steel acupuncture needles (Seirin, Japan) were inserted at PC-6 & ST-36 bilaterally. PC-6 depth-insertion was one body-inch and ST-36 was 1.5 body-inches. De qi sensation was reached. Both electrical and manual stimulations were used. Evaluation and treatment took 30 minutes.
3. Treatment regime	3a) Number of treatment sessions 3b) Frequency and duration of treatment sessions	Five treatment sessions once daily for less than 30 minutes
4. Other components of treatment	4a) Details of other interventions administered to the acupuncture group 4b) Setting and context of treatment, including instructions to practitioners and information and explanations to patients	All patients received concurrent triple antiemetic pharmacotherapy and high-dose chemotherapy. The 2 interventions were "classical acupuncture" or "non-classical acupuncture." Classical acupuncture is a protocol for electroacupuncture at sites that are indicated for nausea and emesis control. Non-classical acupuncture is a protocol of minimal needling near sites that are not indicated for nausea and emesis control with mock stimulation.
5. Practitioner background	5) Description of participating acupuncturists	There were two acupuncture practitioners. One was a clinical instructor at the medical school and had 3 years of acupuncture training; the other was an acupuncture clinician with 20 years of practicing experience.
6. Control/comparator interventions	6a) Rationale for the control or comparator 6b) Precise description of the control or comparator.	A recent NIH report concluded that acupuncture was efficacious in reducing emesis associated with chemotherapy. However, it suspected that such benefit was due to a placebo effect. This trial assesses a standardized electroacupuncture protocol as an adjunct to antiemetic pharmacotherapy for controlling emesis associated with intensive, multiple-drug, combination myeloablative chemotherapy compared with minimal needling or antiemetic pharmacotherapy alone.

Results

- Our evaluation reveals this trial has low risk of bias in all of the five domains according to Cochrane Collaboration's Tool, (*Table 1*) and meets the requirements on the STRICTA checklist (*Table 2*).
- The results of this study reveal that the addition of daily electroacupuncture treatment to the antiemetic regimen was superior to the pharmacotherapy alone or minimal needling in preventing chemotherapy-induced emesis.
- The electroacupuncture group had fewer episodes of emesis than the minimal needling group (P<0.001).
- The minimal needling group had fewer episodes than the antiemetic medication only group (P=0.01).

Conclusions

- The therapeutic outcomes of acupuncture treatments can be contributed to the acupuncture itself in this trial.
- The three-arm study design addresses the non-specific effect or placebo effect.
- Future acupuncture trials need to adhere to the STRICTA Guidelines and the Cochrane Collaboration's Tool for quality assurance, and include control groups to rule out or measure placebo effect.

References

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(3) Shen, J., Wenger, N., Glaspy, J., Hays, R. D., Albert, P. S., Choi, C., et al. (2000). Electroacupuncture for control of myeloablative chemotherapy-induced emesis: A randomized controlled trial. JAMA : The Journal of the American Medical Association, 284(21), 2755-2761

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