Acupuncture for post-tonsillectomy pain: evidence from a recent randomized clinical trial

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The French Society of Otorhinolaryngology (SFORL) published a guideline on the nonpharmacological treatment of post-tonsillectomy pain in 2014 (1). The guideline states that acupuncture for post-tonsillectomy pain remains controversial (level of evidence: 2); additionally, the guideline notes that moderate side effects are found in 11.8% of pediatric acupuncture cases (level of evidence: 2) (1,2).

A prospective, double-blinded, randomized controlled trial of acupuncture for post-tonsillectomy pain was published in 2017 (3). The authors concluded that acupuncture is clinically effective in reducing post-tonsillectomy swallowing pain and may be performed in addition to the administration of standard medications without any relevant side effects (3). There are conflicts between the two reports (1,3); therefore, further trials on acupuncture use in post-tonsillectomy pain are warranted.

In 2009, Sertel *et al.* (4) reported on a patient-assessor-blinded randomized, controlled trial of patients with post-tonsillectomy aged ≥16 years. The trial randomized the subjects (n=123) into three groups [nonsteroidal anti-inflammatory drug (NSAID) plus verum acupuncture, n=41; NSAID plus control acupuncture (non-specific control points on the body), n=41; and NSAID only, n=41]. Verum acupuncture demonstrated pain reduction without side effects (4).

A 2-armed, randomized controlled trial (2015) of conventional postoperative analgesia plus acupuncture (n=30) versus only conventional postoperative analgesia (n=30) (5) and a retrospective review of pediatric acupuncture for postoperative pain in tonsillectomy (2013) (6) both reported positive effects on pain reduction when acupuncture was added to conventional analgesia. A double-blind, placebo-controlled, randomized trial published in 2015 (7) allocated pediatric tonsillectomy patients undergoing standard surgery into a real acupuncture group (n=30) and a Streitberger sham acupuncture group (n=29) to investigate whether pain was reduced by acupuncture treatment. The researchers concluded that intraoperative acupuncture demonstrated analgesic effects and was well tolerated (7). Although these studies (4-7) generally showed positive results for pain reduction with acupuncture use and safety of the technique, there are conflicts within the total body of evidence (1). Why is there a gap between the 2014 evidence and other results?

A recent randomized controlled trial (3) presented moderate risk of bias when assessed by the Cochran risk of bias tool (*Table 1*). In addition, the effect size (ES) and power of the trial had less of an impact on the evidence regarding acupuncture analgesia for post-tonsillectomy pain. Recalculation of results of ES and power (G*Power Version 3.1.9.2 statistical software; Franz Faul, Universität Kiel, Germany) between the verum acupuncture group (n=16) and the sham acupuncture group (n=15) yielded $T_{0/20}$ [ES: 0.35; estimated sample size: 260 (130+130), σ=0.05, β=0.2, 1:1 group allocation ratio, compared means between two independent groups; post hoc recalculated power: 0.16]; $T_{0/60}$ [ES: 0.46; estimated sample size: 148 (74+74); post hoc power: 0.24]; $T_{0/120}$ [ES: 0.27; estimated sample

Table 1 Cochrane risk of bias of the randomized clinical trial

Items	Risk of bias	Reason
1. Random sequence generation (selection bias)	Low	block randomization list (by the Institute of Medical Biometry of the University Heidelberg)
2. Allocation concealment (selection bias)	Unclear	Not reported
3. Blinding of participants and personnel (performance bias)	Patients-blind; low	Verum acupuncture *vs.* sham acupuncture (at nonspecific acupuncture points in the midaxillary line)
	Practitioner-blind; low	Dentist without previous acupuncture knowledge who was blinded to the form of acupuncture (acupuncturist blinded)
4. Blinding of outcome assessment (detection bias)	Unclear	Not reported
5. Incomplete outcome data (attrition bias)	Low	No dropouts
6. Selective reporting (reporting bias)	Unclear	No protocol published
7. Other bias (baseline imbalance)	High	Sex difference (more women than men)

size: 430 (215+215); post hoc recalculated power: 0.11]; and $T_{0/180}$ [ES: 0.25; estimated sample size: 518 (259+259); post hoc recalculated power: 0.10]. Therefore, the trial seemed to be underpowered with insufficient sample size. Clearly, a powered trial with low risk of bias would impact the evidence regarding analgesic effects of acupuncture for post-tonsillectomy patients or postoperative pain management (8,9).

Debates regarding sham acupuncture are ongoing (10). Dingemann *et al.* (3) adopted control acupuncture for practitioner-patient-blinding to acupuncture at nonspecific acupuncture points in the midaxillary line. A validation questionnaire could have been administered to blinded subjects to determine whether blinding was successful (11). Another issue in acupuncture studies is use of the Standards for Reporting Interventions in Controlled Trails of Acupuncture (STRICTA) reporting guideline to improve transparent reporting of acupuncture trials (12). The Dingemann *et al.* study (3) showed scant reporting on items regarding acupuncture rationale, details of needling, other components of treatment, and practitioner background (*Table S1*).

A last issue in acupuncture trials is safety reporting. Dingemann *et al.* (3) noted no significant side effects, but more detailed reporting is required. In contrast, the SFORL guideline reported moderate side effects in 11.8% of pediatric acupuncture patients (2). Future trials should focus on risk of bias, ES, power, use of sham acupuncture controls, use of STRICTA reporting guidelines, and safety.

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Footnote

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Ethical Statement: The author is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Supplementary

Table S1 Checklist for items in STRICTA 2010 of the randomized clinical trial

Item	Detail	Page number
1. Acupuncture rationale	1a) Style of acupuncture (e.g., Traditional Chinese Medicine, Japanese, Korean, Western medical, Five Element, ear acupuncture, etc.)	Traditional Chinese medicine; 3p
	1b) Reasoning for treatment provided, based on historical context, literature sources, and/or consensus methods, with references where appropriate	Not reported
	1c) Extent to which treatment was varied	Not reported
2. Details of needling	2a) Number of needle insertions per subject per session (mean and range where relevant)	3p
	2b) Names (or location if no standard name) of points used (uni-/bilateral)	3p
	2c) Depth of insertion, based on a specified unit of measurement, or on a particular tissue level	Not reported
	2d) Response sought (e.g., *de qi* or muscle twitch response)	Not reported
	2e) Needle stimulation (e.g., manual, electrical)	Not reported
	2f) Needle retention time	3p
	2g) Needle type (diameter, length, and manufacturer or material)	3p
3. Treatment regimen	3a) Number of treatment sessions	3p
	3b) Frequency and duration of treatment sessions	3p
4. Other components of treatment	4a) Details of other interventions administered to the acupuncture group (e.g., moxibustion, cupping, herbs, exercises, lifestyle advice)	2p
	4b) Setting and context of treatment, including instructions to practitioners, and information and explanations to patients	2, 3p; partially reported
5. Practitioner background	5) Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice, other relevant experience)	3p; partially reported
6. Control or comparator interventions	6a) Rationale for the control or comparator in the context of the research question, with sources that justify this choice	4p
	6b) Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details as for Items 1 to 3 above	3, 4p

Note: This checklist, which should be read in conjunction with the explanations of the STRICTA items, is designed to replace CONSORT 2010's item 5 when reporting an acupuncture trial.