Perioperative acupuncture and postoperative acupressure can prevent postoperative vomiting following paediatric tonsillectomy or adenoidectomy: a pragmatic randomised controlled trial

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ABSTRACT

Objective To investigate the effectiveness of acupuncture and acupressure as supplements to standard treatment for postoperative vomiting in children undergoing tonsillectomy and/or adenoidectomy.

Methods A pragmatic, open, block-randomised controlled trial. The results were analysed according to the intention-to-treat principle. The study was conducted without extra resources in a normal setting at the day-surgery department of Lovisenberg Diakonale Hospital in Oslo. 154 children with an American Society of Anesthesiologists grade 1–2, weighing at least 10 kg, were included. Children with concomitant gastrointestinal diseases, emesis or antiemetic treatment <24 h preoperatively, rash or local infection over the actual acupuncture points were excluded together with patients whose parents’ informed consent could not be obtained. The intervention group received acupuncture at pericardium 6 bilaterally, at a depth of approximately 0.7 cm with a median of 21 min during anaesthesia, followed by acupressure wristbands for 24 h and standard treatment. The control group received standard treatment. The primary end point was the occurrence of vomiting or retching during 24 h postoperatively.

Results Children in the acustimulation group experienced less retching and vomiting than the control group—46.8% versus 66.2% (p=0.015). The effect of acustimulation was specifically pronounced in girls and children aged 1–3 years.

Conclusion This trial indicates the effectiveness of acustimulation as an adjunct to standard treatment. The results should encourage and promote the implementation of acustimulation for postoperative vomiting in children undergoing adenoidectomy or tonsillectomy.

INTRODUCTION

Postoperative nausea and vomiting (PONV) is an unpleasant sequel to surgery and anaesthesia. Prolonged postoperative hospitalisation in children is most commonly due to PONV,1 and, in addition to causing distress for the patient, PONV can entail dehydration, metabolic disturbances, increased pain and bleeding.2

The overall incidence of postoperative vomiting (POV) is twice as high in children as in adults.3 After tonsillectomy, PONV occurs in >50% in children.4 5 Parents have ranked POV as the least desirable side effect for their child.6

Risk factors for PONV in adults include female sex, non-smoking status, history of PONV/motion sickness, volatile anaesthetics and opioids, longer duration of surgery and type of operation.7 In children, the risk factors are slightly different. Data on children are often limited to vomiting, ignoring nausea. The incidence of POV increases with age (>3 years) and tapers off in puberty. No sex differences are reported in the youngest children.8

Drug treatment is only partially effective in preventing PONV, and can cause adverse effects, such as sedation, headache and extra pyramidal reactions.7–9 The unwanted POV, the limited effect of antiemetic drugs and adverse effects indicate the need for additional prophylactic treatment. Hence, it is appropriate to consider the use of non-pharmacological methods for preventing PONV. Acupuncture is part of traditional Chinese medicine (TCM), and an integrated part of today’s Chinese healthcare system.10 The efficacy of stimulation of the traditional Chinese acupuncture point pericardium 6 (PC6) as an antiemetic in children has been documented.11 PC6 stimulation is similarly effective across methods of stimulation, whether they are invasive (acupuncture) or non-invasive (acupressure).10 Others have demonstrated that acupuncture is more effective than acupressure in reducing vomiting for children.12

The objective of this study was to investigate the effectiveness of perioperative acupuncture and postoperative acupressure as supplements to standard treatment for POV in children undergoing tonsillectomy and/or adenoidectomy.
MATERIAL AND METHODS
Setting and participants
The study was performed from May to November 2008. Participants were children with written consent from parents/guardians, American Society of Anesthesiologists grade ≤2, aged 1–11 years, weighing at least 10 kg and scheduled for tonsillectomy and/or adenoidectomy at Lovisenberg Diakonale Hospital in Oslo, Norway. Exclusion criteria were (1) parents required an interpreter; (2) inflammation over the relevant acupuncture points; (3) emesis or antiemetic treatment during the previous 24 h; (4) gastrointestinal illness. Parents/guardians were informed about the study in a letter sent beforehand. During the study period, 320 children were admitted to the hospital for tonsillectomy and/or adenoidectomy. Among these, 166 children were not eligible: In 103 cases parents had not read the information, in 28 cases parents did not want to participate. Eleven children had parents who needed an interpreter, 11 operations were cancelled and in seven cases there were other reasons (not specified). Five children had taken antiemetic during the past 24 h and one procedure was discontinued owing to arrhythmia after induction of anaesthesia.

One hundred and fifty-four children were included. Numbers of allocated children were 77 in the intervention group and 77 in the control group. A total of 32 interventions were discontinued because the acupuncture duration or wristband use was shorter than planned according to protocol. None of the children were excluded from analysis (figure 1).

Four anaesthesiologists performed the intervention, all trained by an experienced acupuncturist. Eight surgeons conducted the surgery. The caregivers in anaesthesia and surgery were evenly distributed between the two groups.

Preoperative preparation
The children had not eaten solid food on the day of surgery, but were allowed to drink clear fluids up to 2 h before surgery. The anaesthesiologist examined the child, and, if eligible, he/she was enrolled in the study.

Anaesthetic management
Anaesthetic agents were given according to a standardised regimen, at the anaesthesiologist’s discretion. Sevoflurane 8% in 30% oxygen and 70% nitrous oxide was administered by mask for the induction of anaesthesia. When sufficient depth was attained, sevoflurane was regulated to 3%, an intravenous cannula was inserted and an infusion of 500 ml of Ringer’s acetate started at a non-standardised rate. An orotracheal tube secured the airway. Before the gag was put in place, a bolus dose of 2.5 mg/kg propofol was given intravenously, followed by a maintenance infusion of 12–15 mg/kg/h and remifentanil 0.3–0.7 mg/kg/min. Once the gag was in place, sevoflurane and nitrous oxide were discontinued.

Paracetamol 15 mg/kg and ketobemidone hydrochlo-ride—a strong synthetic opioid analgesic not generally available outside Scandinavia—0.1 mg/kg were given intravenously, and if required, alfentanil 25 μg/kg. All children were given dexamethasone 4 mg intravenously as an anti-inflammatory and prophylactic antiemetic. The children were ventilated mechanically or by hand during anaesthesia. After surgery, the lungs were ventilated with 100% oxygen, and the anaesthetic infusions stopped. When the child was breathing sufficiently, extubation was performed. The different techniques used for the tonsillectomy were knife, loop and scissors with or without diathermy.

Acupuncture point stimulation intervention
While the control group received standard treatment as described, the intervention group in addition received acupuncture point stimulation. Acupuncture with ‘Seirin’ needles no 3 (0.20×15 mm) to a depth of approximately
7 mm, was performed while the child was anaesthetised, using acupuncture point PC6 bilaterally. PC6 is located at the wrist between the tendons of the palmaris longus and flexor carpi radialis, 2 cun proximal from the distal palmar crease. (1 cun is equivalent to the width of the patient's thumb across the interphalangeal joint.)

The acupuncture needles were not stimulated, and were removed before the child woke up. The intended acupuncture time was ≥20 min. After removing the acupuncture needles, elastic wristbands were applied, producing pressure on the PC6 acupuncture points bilaterally by means of a plastic stud. If bleeding or bruising occurred caused by the needle insertion, the wristband served as a pressure bandage. The wristbands were worn for 24 h, if tolerated. There was no way of adjusting the pressure of the wristbands, which were delivered in children's size and free of charge by Sea Band UK Ltd, through B&T Acupressure, Oslo, Norway (figure 3).

Postoperative care
Postoperative pain was treated in the recovery unit with ketobemidone intravenously. The use of antiemetic was restricted to persistent PONV, as it was considered that vomiting, by emptying the stomach of blood, might alleviate PONV. Further administration of intravenous Ringer's acetate solution was regulated at the anaesthesiologist's discretion.

Children, who underwent adenoidectomy, were offered clear drinks after 30 min. Soft, cold or lukewarm food was permitted after 2 h. After tonsillectomy, drinking and flavoured ice was allowed after 2 h, eating after 6 h. The stay in recovery was for a minimum of 2 and 4 h, respectively. Children aged <3 years who underwent tonsillectomy stayed at the hospital overnight, as did other children at the surgeon/anaesthesiologist's discretion.

Data collection
The parents/guardians had completed a form beforehand specifying factors with potential influence on PONV: the child's history of PONV and motion sickness, parents' history of PONV and whether the child was exposed to tobacco smoke at home. Checklists for the anaesthesiologist and recovery nurse were used to ensure that all required data were registered.

The anaesthesiologist recorded the duration of acupuncture and the point of time of wristband application in the perioperative record. This record also included data on age, type of surgery, drugs and anaesthesia time. The use of opioids and antiemetics was registered during the recovery period only, lasting from 2 to 6 h. Any occurrences of retching or vomiting in the first 24 h were registered in a self-composed form. Retching and vomiting recurring within a period of 2 min were considered as one occurrence. The recovery nurse recorded data during the recovery period, and after discharge this was done by the parents/guardians. The parents/guardians also recorded how long the child kept the wristbands on, and any adverse effects from the acustimulation. The parents gave their subjective opinion on the degree of discomfort the child had experienced from PONV, from the range: none, minimal, moderate, great, to severe.

The principal investigator (IL) collected the data registered by the parents/guardians by telephone, and any missing baseline data were completed. In order to obtain complete collection of data, the principal researcher consecutively followed up and surveyed the personnel involved.

End points
The primary end point was the occurrence of vomiting or retching during 24 h postoperatively. Secondary end points were the effect of acupuncture point stimulation with regard to associations with possible factors of predisposition to PONV.

Statistics
According to previous experience (Ariansen, unpublished observations, 2004), the incidence of vomiting and retching was 35% among children undergoing ear, nose and throat surgery at this hospital receiving the standard treatment. We considered a reduction of vomiting to an incidence of 25% to be a clinically important result. With a power of 0.8 to detect a 25% difference in the incidence of PONV with a significance level of 0.05, the sample size calculation required 126 children. To ensure an adequate sample size for the heterogeneous mix of children, and taking into account dropout and withdrawal, we exceeded this sample size. The outcomes were analysed according to the 'intention-to-treat' principle. Non-compliance and non-adherence were considered as parts of the results, so that the outcomes attained would be of direct relevance to normal practice.14

All data were converted into SPSS (version 17.1) and analysed by frequency distribution and bivariate descriptive statistics. Categorical variables were compared using χ² tests. Statistical significance was identified by descriptive bivariate analysis as well as by logistical regression analysis. A p value <0.05 was considered statistically significant.

RESULTS
Patient characteristics and treatment/intervention data are presented in table 1.

A statistically significant lower proportion of children in the acustimulation group experienced retching or vomiting than in the control group, 46.8% versus 66.2% (p=0.015) (table 2). This difference was also expressed in the parents' overall subjective evaluations of their children's experience of discomfort (table 2).

Another finding was that the effect of acustimulation may be more pronounced in girls (p=0.004) and children aged 1–3 years (p=0.025) (table 2). A logistic regression analysis showed that age and sex were significant, independent variables for vomiting/retching (table 3).

The results also showed a tendency for a better effect of acustimulation among children with less pronounced vomiting but this was statistically insignificant (figure 2).
There was no significant difference in the occurrence of POV among children with a history of motion sickness or PONV, compared with those without those predispositions. Children without a previous history of motion sickness or PONV receiving acustimulation had less POV, \( p=0.002 \) and \( p=0.012 \), respectively (table 2), than the control group. Neither parents’ own experience/history of PONV, nor the child’s exposure to tobacco at home, were associated with the outcome.

Acustimulation appeared to reduce POV in children undergoing adenoidectomy or tonsillectomy, \( p=0.036 \) and \( p=0.020 \), respectively (table 2). In children with a combined surgical procedure, there was no significant difference. The duration of surgery and/or duration of anaesthesia was not related to the effect; neither was the duration of acupuncture or acupressure. There was no difference in the preoperative use of alfentanil or the postoperative use of ketobemidone between the two groups, and none of the children received rescue medication for PONV during their stay on the postoperative ward.

Twelve children reported adverse effects from acustimulation. Eight children experienced the wristbands as tight, three children complained about itching and one child expressed concern about both tightness and itching. There were no reports of local/dermatological problems or bleeding at the acupuncture site.
This study indicates the effectiveness in the prevention of POV of acustimulation in children undergoing adenoidectomy or tonsillectomy. Previous studies have shown the efficacy of acustimulation, using invasive and non-invasive methods, on POV in children undergoing different types of surgery, including tonsillectomy.15–18

Two findings are worth mentioning: girls possibly benefit more than boys from acustimulation, and younger children ≤3 years possibly benefit more than older children. To the best of our knowledge, no previous studies on acustimulation for POV have reported gender differences in children, or stratified POV according to age in children. However, this study was not powered to detect subgroup differences. When interpreting these results, it is important to bear in mind that the subgroup analyses were not planned a priori; hence, they are post hoc analyses—and should be interpreted with great caution. These findings deserve further investigation.

In accordance with previous studies on postoperative emesis,2 we found that the youngest children suffered less from POV than the older children. We also found that girls suffered more POV than boys. Why does acustimulation favour girls, who are more at risk, and younger children, who are less at risk? A tentative explanation of the former may be the obvious sex hormone differences between girls and boys. Acustimulation may be more effective on nausea induced by oestrogens/progestogens. In the case of younger children they may receive more benefit from acustimulation than older children because they are more sensitive to tactile/neurogenic stimuli.

A previous history of nausea and vomiting has been claimed to predispose for PONV.2 Smoking has been reported to protect against PONV in adults,19 and presumably, passive exposure to tobacco might protect children against POV. Our study provides no evidence for such effects.

We have scrutinised the minimal response to acustimulation of children who underwent the combined operation of adenotonsillectomy. Neither age nor gender influenced this result, and for this we found no reasonable explanation.

Following the routines in the anaesthesiology department, all children received the same dose of dexamethasone. This would have led to a greater effect on younger children as it comprises a bigger dose in smaller patients. However, this would not have affected the results, as the age was evenly distributed between the two groups.

No adverse events from the acupuncture were reported. Commonly, adverse events in children are redness and numbness at the acupuncture site, light-headedness and needle pain.20 Anaesthesia precluded the children from experiencing needle pain and the sensation of light-headedness.

This study shows an incidence of POV rate, nearly twice the estimated incidence in the previous investigation in our department (Ariansen, unpublished observations, 2004). However, the data from this previous investigation were the best available from our department for the pre-study sample size calculation.

Parents’ willingness to consent may cause selection bias towards participation for children with parents having a positive attitude towards acupuncture.21 We excluded parents in need of an interpreter, owing to the importance of understanding information and instructions. This limits the generalisability of the results.

The absence of blinding may influence the measured treatment effect and create information bias. A positive attitude of parents towards acupuncture may lead to an overestimation of its benefit.21 However, according to the pragmatic approach, caregivers and patient biases are not regarded as detrimental, but accepted as part of the responses to treatment, as this will best reflect the likely clinical response in practice.22 Blinding the assessor of outcomes to the children’s treatment status was not possible, because of the nature of the information concerning acupressure time and adverse effects.

Another aspect of a possible information bias is ‘eager-to-please’. Participants most often want things to turn out well, and want to be cooperative. Parents’ attitudes may have affected their reports and skewed the results in a more positive direction.

Parents’ evaluation of the child’s total experience of discomfort was based on their subjective interpretation. Their impression of degree of discomfort might have differed, as they may have different views on what should be regarded as discomfort. The reliability of the results may thus be questioned.

There is always a chance of performance bias, especially when the treatment is entrusted to the patients, or as in this case, to both children and parents. The children were probably prone to rotate the wristbands, and the parents were probably not able to survey the position at all times. This could dilute the effect of the intervention and diminish the differences between the groups.

No data were missing as a result of detailed checklists and a meticulous follow-up of parents and personnel by the principal researcher.

In TCM acupuncture, customised treatment is a fundamental principle. Acknowledging this, it may be considered inappropriate to design a trial based on a standardised intervention.23 Access to the PC6 acupoints during ear, nose and throat surgery is easier than for other points.

Table 3 Logistic regression analysis on significant risk factors related to vomiting/retching

<table>
<thead>
<tr>
<th>Logistic regression dependent variable</th>
<th>Independent variable with statistical significance</th>
<th>p Value</th>
<th>OR (95% CI)</th>
<th>Exp (B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vomiting/retching</td>
<td>Age &gt;3 years</td>
<td>0.001</td>
<td>4.111 (1.836 to 9.206)</td>
<td></td>
</tr>
<tr>
<td>Vomiting/retching</td>
<td>Female sex</td>
<td>0.002</td>
<td>3.329 (1.529 to 7.247)</td>
<td></td>
</tr>
</tbody>
</table>
and the use of wristbands for acupressure is convenient. For these reasons, especially in a pragmatic study where feasibility is important, the PC6 points were chosen. An additional aspect is that standardised intervention is more justifiable in relation to safety considerations, especially when the personnel performing the needling were not trained acupuncturists.

Children who are awake may be unwilling to accept acupuncture needling. We therefore performed the acupuncture during anaesthesia. This procedure precluded needle fine-tuning—that is, using the needle sensation (de qi). The depth of needle insertion was standardised. The performance of acupuncture might have compromised its effect to some degree, but the alternative might lead to complicated procedures unlikely to work in clinical practice. The mode of acupuncture enabled a successful implementation, and satisfied the need for a procedure that was easy to accomplish.

One may question which type of stimulation is the more important: acupuncture or acupressure. Would a simplification of the method, using only one ‘acu-mode’, be sufficiently effective? Previous studies have suggested that acupuncture administered after the induction of anaesthesia may have little or no effect,24 25 and, furthermore, that acupressure may prolong the antiemetic effect of acupuncture.26 27 We presumed that by using both modes we would attain an incremental/optimal effect, which seemed particularly valuable in a pragmatic study.

Balancing internal and external validity is a well-known challenge in pragmatic trials.28 We applied some exclusion criteria, used randomisation with various block sizes and used a simplified, standardised intervention to maintain an acceptable internal validity. The lack of blinding in the study reduces the internal validity. However, there is likely to be a trade-off as the generalisability to clinical setting is better (external validity). The use of placebo was considered to be inappropriate for the research question.29 Our aim was to gain knowledge of whether the intervention might be a clinically relevant supplement to standard treatment, which, accordingly, was chosen as comparator. Moreover, the use of sham acupuncture as placebo intervention is controversial. The term placebo control implies the use of a truly inert intervention, and any control treatment that involves invasive needling is not truly inert.30

Current evidence of the efficacy of acustimulation in reducing POV in children is based largely on explanatory randomised controlled trial designs, and all studies but one,31 involve placebo (sham) as comparator. These explanatory randomised controlled trial designs generated a strong internal validity, but the external validity is weaker. The pragmatic approach in this study focuses on the system efficacy—that is, the efficacy of the complete treatment package, including non-specific effects. This practical procedure will possibly generate more relevant knowledge for implementation of acustimulation as a supplement to standard treatment.

**CONCLUSION**

This trial indicates the effectiveness of acustimulation for POV as an adjunct to standard treatment in children undergoing adenoidectomy or tonsillectomy. The results should encourage and promote the implementation of acustimulation for postoperative vomiting in children undergoing tonsillectomy or adenoidectomy.

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**Summary points**

- Acupuncture and acupressure are known to reduce post-operative nausea and vomiting.
- We compared their effect against usual care alone, in children following tonsillectomy or adenoidectomy.
- Vomiting occurred in 47% of children with acupuncture and 66% of children without (P=0.015).
University of Tromsø (NAFKAM).

Competing interests  None.

Contributors  MH, ASS, VME, EKB, TA and AJN contributed to the conception and design of the study. MH contributed to the acquisition of data. EB contributed his statistical knowledge. All authors participated in the analysis and interpretation of data. They also drafted the article and revised it critically for important intellectual content; and approved the version to be published.

Ethics approval  The regional ethics committee (Ref: 200704180-5/A/Y/400) approved the study, which was carried out in accordance with the Helsinki Declaration.

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