Original Article

Intraoperative acupuncture as complementary analgesic for post-tonsillectomy pain in children—a prospective randomised clinical trial of effects and safety

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Background: Tonsillectomy in children is usually accompanied by significant morbidity, including postoperative bleeding, pain, nausea, vomiting, poor oral intake and dehydration. Recent evidences in literature suggest that acupuncture could play a role in reducing postoperative pain in these children. This study aims to investigate the effect of intraoperative acupuncture on postoperative pain scores and oxycodone requirements in children following elective adenotonsillectomy in a prospective randomized controlled trial.

Methods: A total of 251 healthy children undergoing tonsillectomy or adenotonsillectomy, aged between 2 and 10 years old, were randomly assigned to either control or acupuncture groups. Preoperative block randomisation and allocation concealment were performed. All patients received standardised anaesthesia and surgery including intraoperative Morphine, Dexamethasone, Granisetron, Clonidine and Paracetamol. In the acupuncture group, acupuncture was additionally applied at 10 specified points immediately after induction of anaesthesia. Postoperative pain relief consisted of Paracetamol regularly and Oxycodone as required. All patients, nursing staff and parents were blinded. All assessments of postoperative pain was evaluated using the Face, Legs, Activity, Cry, Consolability (FLACC) pain scale. Pain scores were recorded at regular intervals during the first 24 hours in hospital and on days 1, 2 and 5 at home following discharge.

Results: There were 130 patients in control group and 121 patients in acupuncture group. Acupuncture treatment provided significant benefit for the initial postoperative pain. Pain scores were significantly lower in the acupuncture group compared to those in the control group in the first 12 hours but no difference was noted after discharge at home. There was no difference in the oxycodone requirements between the two groups in hospital but a significant reduction was noted in the acupuncture group on Day 2 at home. No significant adverse effects related to acupuncture treatment were observed.

Conclusions: Our study lends support to other findings in the current literature that acupuncture is an effective supplemental tool for reducing early postoperative pain and Oxycodone requirement at home in children following adenotonsillectomy.

Trial registration: Australian New Zealand Clinical Trials Registry: ACTRN12619000922178.

Keywords: Paediatric acupuncture; paediatric pain; tonsillectomy

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Introduction

Tonsillectomy is one of the most commonly performed surgical procedures in children and often accompanied by significant postoperative morbidity, including bleeding, pain, nausea, vomiting, poor oral intake and dehydration.

Most strategies for managing postoperative pain after tonsillectomy utilise oral drug combinations such as paracetamol or acetaminophen, non-steroid anti-inflammatory drugs (NSAIDS), gabapentin and opioids (1-4). However, post-tonsillectomy pain can lead to poor oral intake and hence limit the effectiveness of such treatment.

As a non-drug treatment, acupuncture may be useful in complementing the analgesic effect of these postoperative drugs and reducing their side effects (5-8).

We designed a randomised, controlled trial to examine the effect of intraoperative acupuncture on postoperative pain in children undergoing adenotonsillectomy. We present this article in accordance with the CONSORT guidelines (available at http://dx.doi.org/10.21037/ajo-19-74).

Methods

The study was conducted in accordance with the National Statement on Ethical Conduct in Human Research [2015] and was approved by the Greenslopes Research and Ethics Committee and the St Vincent's Health and Aged Care Human Research Ethics Committee. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

We enrolled 251 children undergoing elective adenotonsillectomy into our study.

All children were aged between 2 to 10 years old and otherwise healthy with ASA 1 or 2 status.

Exclusion criteria included any significant allergy, known bleeding tendency, known or likely airway difficulty and children who had received acupuncture, analgesics or sedatives within 36 hours prior to surgery.

All suitable patients (253 in total) were invited to participate in the study and all but 2 of the parents accepted and consented. One parent felt that the whole hospital experience was too stressful and did not want any additional stress. The other parent did not give a reason for the refusal.

All parents gave written informed consent prior to surgery. All parents were interviewed and consented by the anaesthetist the night before or on the day of surgery. All were given a chance to ask questions at the interview and any queries were addressed prior to the procedure.

The patients were randomised in blocks of 50 and assigned by a computer-generated programme to either a control or acupuncture group. To minimise allocation bias, this procedure was undertaken by an independent collaborator. On the day of surgery, the independent collaborator would receive the names of the patients and then allocate the patients into the respective groups. The anaesthetist was informed just prior to the procedure of their allocations. The patients and all subsequent persons recording the pain assessments including parents, recovery nurses, ward nurses and follow-up research nurses were blinded as to which group each patient was assigned.

In the operating room, the same designated drugs, in particular Morphine, Granisetron, Dexamethasone, Clonidine and Paracetamol were drawn up in the correct weigh adjusted dosage by the anaesthetist prior to starting the procedure and crossed-checked by an independent anaesthetic nurse assigned to the list for that day to minimise bias in drug administration.

In the control group, each child was accompanied by their parent into the operating room for induction. General anaesthesia was induced by 40% oxygen, 60% nitrous oxide and 8% Sevoflurane until loss of consciousness. The parent was then escorted out of the operating room. An intravenous cannula was inserted and the child was given morphine 0.1 mg/kg, granisetron 20 mcg/kg, dexamethasone 0.1 mg/kg, clonidine 1 mcg/kg and paracetamol 15 mg/kg intravenously. A flexible laryngeal mask (LMA) of the appropriate size was inserted to maintain the airway for the duration of surgery and recovery. Anaesthesia was maintained with oxygen 100% and end-tidal sevoflurane of 4–6% with spontaneous ventilation. An intravenous fluid bolus of 10 mL/kg was given intraoperatively and followed by 1 mL/kg/h in the ward. The adeno-tonsillectomy procedure was performed by blunt dissection and electrocautery. At the conclusion of surgery, the child was transferred onto a ward bed and taken to recovery with the LMA *in situ*. The LMA was removed in recovery when the child was awake and able to maintain his/her own airway.

In the acupuncture group, an identical procedure to that described above was followed with the addition of the insertion of ten (9) acupuncture needles after LMA insertion and prior to surgical stimulation. All acupuncture was performed by a single anaesthetist who had prior certification from the Australian Medical Acupucnture

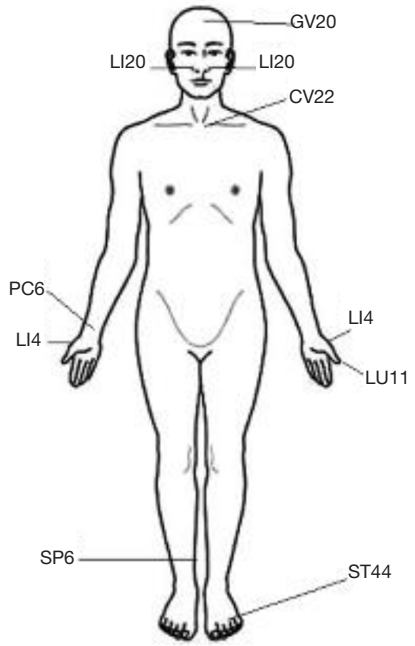

Figure 1 Acupuncture points.

College (AMAC). Stainless steel acupuncture needles, 15 mm in length and 0.18 mm in diameter (Serin Co, Shizuoka, Japan), were used. The sites of needle insertion, in accordance Chinese Medicine standards, were: LI4 bilaterally, LI20/Bitong bilaterally, CV(REN)22, GV(DU)20, LU11, PC6, ST44, SP6 (*Figure 1*). These particular acupuncture points were selected for their local analgesic properties in the nasopharyngeal region or for their general analgesic and anti-inflammatory properties. No electrical stimulation or manual stimulation was applied to the acupuncture needles. Surgery was commenced immediately following the acupuncture needle insertion. The needles were left *in situ* for the duration of surgery, and immediately removed at the completion of surgery prior to the transfer of patient to recovery room.

In recovery and on the ward, all patients were assessed for pain using the Face, Legs, Activity, Cry, Consolability (FLACC) pain scale (*Figure S1*) by nursing staff. The FLACC Pain Scale is a widely used behavioural observation pain scales to quantify procedural pain in infants and young children (10) and has been shown to be particularly useful in assessing postoperative tonsillectomy pain in paediatric patients (9).

In recovery, at intervals of 10, 20, 30, and 45 minutes after awakening, if the child showed evidence of significant pain with a pain score of ≥7 on the FLACC scale which was unrelieved by simple comfort measures including nursing by parents or taking oral ice blocks, he/she was treated with a Morphine bolus of 50 mcg/kg. The patient was also assessed for nausea and vomiting and treated with Droperidol 10 mcg/kg if required. When the child was awake, alert and comfortable, he/she was discharged to the ward with the accompanying parent and ward nurse.

On the ward, all patients were given regular Paracetamol 15 mg/kg orally every 6 hours. If the child showed evidence of significant pain with a pain score of ≥7 on the FLACC scale, oxycodone liquid 0.1 mg/kg was given at 4 hourly intervals as required at the discretion of the ward nurse. All patients were encouraged to eat and drink as tolerated. All observations, including pain score and pulse oximetry, were recorded by the ward nurse at 1 to 2 hourly intervals, together with the time and dose of oxycodone administered postoperatively. All patients were given another dose of Dexamethasone 10 mcg/kg orally on the first postoperative morning. They were then discharged if they were able to eat and drink. If the patient was still in significant pain, or not tolerating oral intake, then he/she would remain in hospital until these issues were overcome.

All patients were followed up by telephone interview on days 1, 3 and 5 after discharge from hospital by a blinded, independent research nurse. A pain assessment was made at home for each morning, afternoon and evening by the parents using the same FLACC scale.

For concealment, all patient details were entered into a cloud-based database by the blinded collaborator and the results subsequently were entered by the blinded research nurses.

The primary objective of this study was to assess if intraoperative acupuncture can reduce the postoperative pain score for children following adenotonsillectomy as measured by the FLACC pain scale.

A secondary objective of the study was to assess if intraoperative acupuncture can also reduce the oxycodone requirement for children following adenotonsillectomy.

Power analysis

During our ascertainment period in the first nine months of 2015, we observed that by using supplemental acupuncture intraoperatively, there appeared to be approximately a one-third reduction in the dose of intraoperative Morphine required to achieve similar patient comfort level in recovery. Subsequent assessment of our preliminary study data suggested a 30% to 35% postoperative reduction in the

Pain Scores with the addition of intraoperative acupuncture. Based on these observations, we estimate that between 100 to 150 patients are required in each group to achieve a level of statistical significance (P<0.05) at a power of 90% (*Figure S2*). We also noted that an earlier study with a similar design to ours used an initial 35% difference to arrive at a sample size of 30 for each group but was subsequently found to be underpowered (11). A subsequent editorial examined the results of that study and their power recalculation was made post-hoc, revealing an estimate sample size of 260 patients was required for statistical significance (12). Our own power analysis resulted similarly in a sample size of 258 patients, which was comparable to the number of patients [251] enlisted in our study during the 18 months period.

Statistical analysis

All statistical analysis was performed by an independent statistician. Differences in demographic data were analysed using t-tests for continuous variables and chi-squared tests for categorical variables. Outcome data were analysed using simple linear regression for continuous variables and logistic regression for categorical variables. Data analysis was conducted using Stata v14.2 (StataCorp, College Station, TX, USA).

Results

We recruited 251 patients between June 2016 and September 2018 in the study, and all completed the protocol for measurements of the primary and secondary objectives. Of the 251 children enrolled, 121 (48%) received acupuncture in the treatment group and 130 (52%) were in the control group.

Figure 2 shows the CONSORT diagram, and *Table 1* shows the distribution and characteristics of patients. There was no demographic difference between the acupuncture and the control groups.

Differences in Pain Scores between the two groups are shown in *Table 2* and *Figure 3*.

Patients who received acupuncture experienced significantly less pain than the patients in the control group during their stay in hospital (*Table 2* and *Figure 3*). In the Recovery Room, although the Pain Score at 10 minutes postoperatively did not show significant difference at P=0.52, the Pain Score at 45 minutes showed strong evidence of difference at P=0.036. On the ward, the differences in Pain Scores between the acupuncture and control groups were even more noticeable. There was strong evidence of differences in Pain Scores between the two groups from 2 to 12 hours postoperatively, with all recordings within this period showing a statistically significant reduction in pain in the acupuncture group (P=0.001–0.044).

In the latter portion of the patients' hospital stay between 18 and 24 hours post-operatively, the evidence of differences in the groups' Pain Scores were much weaker, trending away from statistical significance, with P=0.096 at 18 hours and P=0.472 at 24 hours. It should be noted that less data were recorded at his later time because either it was night time and these children were not disturbed from sleep or because the children undergoing an afternoon procedure were not present for this period if they were routinely discharged the following morning.

While a number of patients reported high Pains Scores at times, a large proportion of patients reported their Pain Score as zero, causing the data distribution to skew towards zero. This accounts for the lower mean Pain Score than expected at all time points. As expected with paediatric pain assessments, there is a very high degree of variability, as exemplified by the large standard deviation. However, given our large sample size, we were able to perform a linear regression which demonstrated significant differences between the groups. This means that while the differences in Means between control and acupuncture groups may be small, they reflect much bigger differences in actual Pain Scores between patients due to the skewed distribution and high variability.

There were no statistically significant differences in Pain Scores following discharge between the treatment and control groups at home.

However, there were a number of parents who did not return the follow-up telephone calls and as such, our data set is much smaller, with only 168 respondents out of a total of 251 (67%) represented, including 85 patients in control group (34%) and 83 patients in acupuncture group (31%).

There was no statistical difference in the dose of Oxycodone administered in hospital between the two groups (*Table 3* and *Figure 4*). However, an overall trend of lower Oxycodone requirement was noted in the acupuncture group at home over all three days recorded, reaching statistical significance (P=0.035) on postoperative day 2 (*Table 4* and *Figure 5*).

There were no clinically significant complications resulting from the acupuncture treatment, with no local

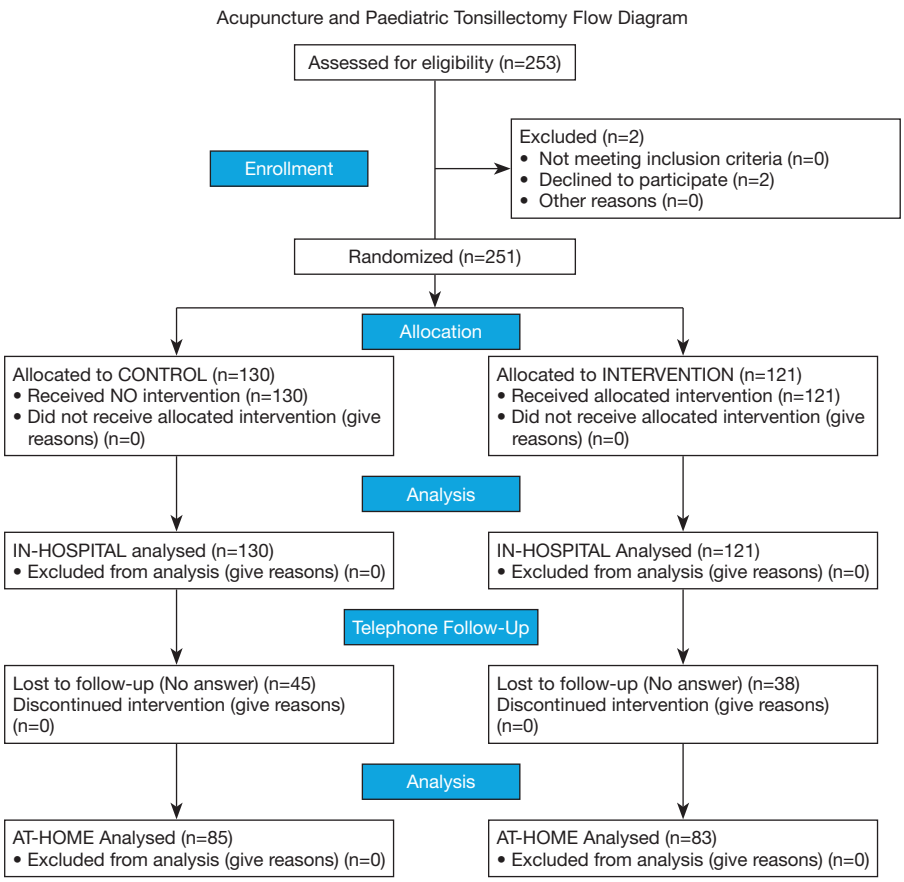

Figure 2 CONSORT diagram for the trial.

Table 1 Demographic characteristics

Characteristics	Control (n=130)	Acupuncture (n=121)
Age, years	4.6 (2.1)	4.9 (2.1)
Weight, kg	21.6 (8.9)	21.0 (8.4)
Sex, male	82	80
Duration of surgery, min	24.8 (7.7)	25.2 (7.1)

Values are shown as mean (SD) or number (proportion).

neurological or systemic complication reported by the staff or the parents. The only notable complication was minor bleeding at the sites of needle insertion following their withdrawals, occurring in 3 patients (2.5%), most commonly around the alar area (LI20) and the thumb nail (LU11). This was treated with locally applied pressure and in all cases, stopped within 10 seconds, before the patients were transferred to recovery. Unlike most other studies (13,14), erythema around the needle insertion sites was uncommon, being noted in only 2 patients (1.7%), around the thenar eminence (LI4). No haematoma was noted or reported in any patients.

Overall, 16 patients were readmitted for postoperative bleeding (6.4%), with 8 patients each from control and acupuncture group. Of these, 6 patients (2.4%) returned to operating theatre for control of bleeding, comprising of 3 patients each from control and acupuncture groups. In addition, 4 patients were re-admitted following discharge. Two patients had poor pain control and were not tolerating oral medications, both from the control group. Two patients

Table 2 Differences in pain score between control and acupuncture groups at each time-point

Pain score period	Control			Acupuncture			Simple linear regression	
	N	Mean	SD	N	Mean	SD	Coefficient	P value
PS 10 min	130	2.8	3.2	121	2.1	2.7	−0.7	0.052
PS 20 min	130	2.1	2.6	121	1.8	2.4	−0.3	0.336
PS 30 min	115	1.5	2.4	105	1.2	1.8	−0.4	0.205
PS 45 min	69	1.3	2.4	63	0.6	1.2	−0.7	0.036
PS 1 h	130	0.9	1.8	120	0.5	1.2	−0.4	0.058
PS 2 h	129	1	1.8	119	0.3	0.8	−0.7	0
PS 3 h	129	0.9	1.7	117	0.4	0.9	−0.5	0.005
PS 4 h	129	1	1.8	118	0.3	0.8	−0.7	0
PS 6 h	128	1.1	1.9	117	0.3	0.9	−0.8	0
PS 8 h	127	1	1.8	116	0.5	1.1	−0.4	0.027
PS 12 h	124	0.8	1.6	115	0.4	1	−0.4	0.044
PS 18 h	111	0.6	1.5	108	0.3	0.9	−0.3	0.096
PS 24 h	50	0.4	1	61	0.2	0.7	−0.1	0.472
PS Day 1 am	83	3.8	2.7	84	3.8	2.6	0.1	0.902
PS Day 1 pm	83	3	2.5	85	3.3	2.4	0.3	0.368
PS Day 1 night	82	4.3	2.6	85	4.3	2.7	0	0.908
PS Day 2 am	83	3.6	2.4	85	3.3	2.4	−0.3	0.373
PS Day 2 pm	83	2.6	2.6	85	3	2.5	0.5	0.23
PS Day 2 night	83	4.2	2.6	85	4.1	2.7	−0.1	0.786
PS Day 5 am	81	3.5	2.5	84	3.2	2.5	−0.3	0.475
PS Day 5 pm	81	2.6	2.6	84	2.7	2.6	0.2	0.676
PS Day 5 night	80	4.1	2.6	79	4.1	2.8	0	0.974

were admitted for a likely viral upper respiratory tract infection, both from the acupuncture group.

Discussion

In Australia, pain relief following adenotonsillectomy in children commonly consists of Paracetamol, Non-steroidal anti-inflammatory drugs (NSAIDs), and narcotics such as oral Oxycodone or Codeine. Although such treatment is generally highly effective, the use of opioid medications can precipitate or exacerbate nausea, vomiting, respiratory suppression or occasionally, as seen in some well-publicized cases, result in fatalities (15).

Our results show that acupuncture is an effective supplemental adjunct for optimizing postoperative pain relief in children undergoing adenotonsillectomy. While our current drug regimen is largely satisfactory, with most children reporting adequate pain control during their stay in hospital, it was enhanced by the addition of intraoperative acupuncture treatment. This was particularly noticeable in the period between 2 and 12 hours postoperatively, during which there were statistically significant differences in pain scores between the acupuncture and control groups. This is a particularly important period for these children because they are normally awake, active, eating and drinking during this time.

In contrast to the significantly lowered pain score in the acupuncture group, there was no significant differences

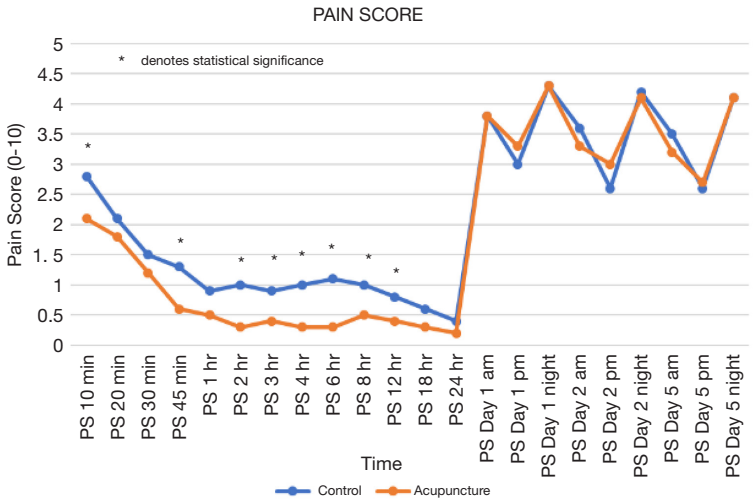

Figure 3 Differences in pain score between control and acupuncture groups at each time-point.

Table 3 Differences in oxycodone administered between control and acupuncture groups in hospital

Oxycodone in hospital	Control			Acupuncture			Simple linear regression	
	N	Mean	SD	N	Mean	SD	Coefficient	P value
Dose of Endone in recovery	8	1.9	0.6	5	2.4	0.5	0.5	0.174
Dose 1 of oxycodone in ward	105	2	0.9	96	2	0.8	0	0.954
Dose 2 of oxycodone in ward	70	1.9	0.8	65	2	0.8	0.1	0.519
Dose 3 of oxycodone in ward	32	1.9	0.9	28	2.4	2.1	0.6	0.185
Dose 4 of oxycodone in ward	10	2.7	3.5	6	1.7	0.5	−1	0.489

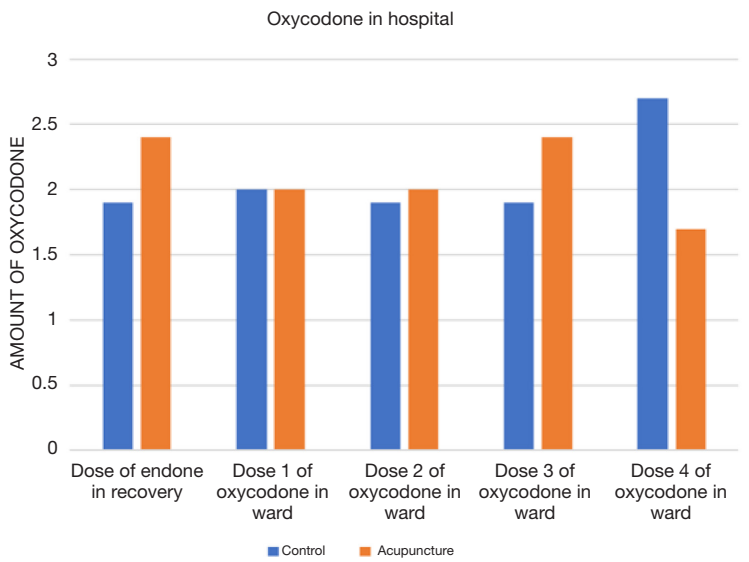

Figure 4 Differences in oxycodone administered between control and acupuncture groups in hospital.

Table 4 Differences in number of doses of Oxycodone administered at home

Oxycodone at home	Control			Acupuncture			Simple linear regression	
	N	Mean	SD	N	Mean	SD	Coefficient	P value
Day 1	80	1.4	1.2	82	1.2	1.1	−0.2	0.253
Day 2	80	1.4	1.3	80	1	1.1	−0.4	0.035
Day 5	78	1.2	1.3	76	1.1	1.3	−0.2	0.36

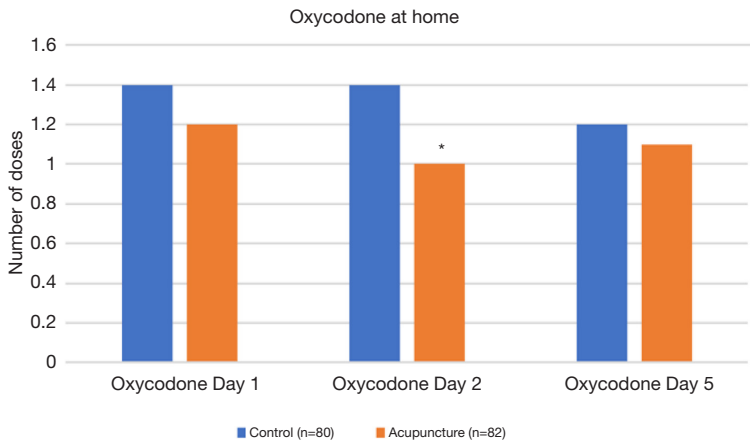

Figure 5 Differences in number of doses of oxycodone administered at home. *, statistical significance (P<0.05).

between the two groups in terms of the number of doses or the amount of oxycodone given in hospital. While there was an overall lower trend for fewer doses given in the acupuncture group in comparison to the control group, it did not reach statistical significance. This was both surprising and disappointing, as we would have expected a lower pain score to result in a reduced requirement for a rescue medication such as oxycodone. These results might reflect a flaw in our methodology, in that we did not communicate and educate our ward nurses sufficiently about our study. It is probable that the nurses on the ward have routinely given the children oxycodone for postoperative pain prior to the study and continued to do so during the study, even if the pain score was reduced. In particular, some nurses routinely gave children oxycodone before bedtime to reduce the possibility of them waking up in pain at night, instead of using it as needed, and thus potentially obscuring any possible benefit from acupuncture at this time. This would fit in with the measured mean time to first dose of oxycodone of between 8 and 10 hours, which was slightly longer in the acupuncture group (9.44±4.75) than the control (8.39±5.0) but did not reach statistically significance (P=0.13).

In our follow-up at home, there was no demonstrable difference in pain scores between the two groups during the first 5 days following discharge from hospital. However, there is an overall lower oxycodone requirement in the acupuncture group at home in all three measuring days. In particular, there was a significant decrease in the number of oxycodone doses required in the acupuncture group on day 2. This could possibly be due to the well-being effects of acupuncture (16). It may be that the acupuncture children recovered better, being more active and feeling better than the control children in the postoperative period at home, resulting in less need for oxycodone.

We cannot readily account for the discrepancies between the pain score and the oxycodone requirement at home. One explanation could be that these pain scores at home were recorded by parents and not by nurses, resulting in greater variability. Parents only measured pain score 3 times a day at home which is much less frequent than the 1 to 2 hour interval measurements in hospital, resulting in less accuracy. It may also be that the timing of the oxycodone doses coincided with the time of pain score measurements,

thus partly obscuring any noticeable differences between the two groups. In any case, a reduced postoperative requirement for oxycodone would be a strong argument in favour of the use of intraoperative acupuncture in children undergoing adenotonsillectomy.

To extend the benefits of acupuncture further into the postoperative period, we could have utilised a number of additional techniques, such as intraoperative electroacupuncture, repeated acupuncture on the ward and/or attaching indwelling acupuncture micro-pins prior to home discharge. However, we considered these techniques to be more invasive and hence less likely to be accepted by parents and children. In our similar concurrent study of acupuncture for post-tonsillectomy pain in adults, in addition to intraoperative acupuncture, we inserted indwelling micro-pins on patients' earlobes, as part of a well-described auricular acupuncture technique, to assess the benefits of ongoing acupuncture treatment at home. This seemed to be very well tolerated by our adult patients and may be applicable in children in future.

Recent evidences in literature indicate that acupuncture may have a role in reducing postoperative pain and vomiting for tonsillectomy in children (5-8). This would then reduce their opioid requirement and, in turn, reduce undesirable drug side effects.

In a study of 143 adult patients, Sertel *et al.* showed that acupuncture significantly reduced odynophagia following tonsillectomy; however, this study employed only post-procedure inpatient acupuncture combined with NSAIDs administration (5). It suggests that acupuncture may be as effective as NSAIDs for treating odynophagia following tonsillectomy.

In a similarly designed study of 60 children, Gilbey *et al.* showed that, in the treatment group, there was less pain, reduced oral analgesic requirement, and higher patient/parent satisfaction with analgesic treatment scores (7). No adverse effects were recorded. They concluded that acupuncture, in addition to conventional analgesic treatment, is an effective treatment for post-tonsillectomy pain. They also noted that acupuncture is safe and well received by children and their parents.

Both these studies suggest that acupuncture may have a significant role in reducing postoperative tonsillectomy pain. However, performance of acupuncture in children who are awake is unlikely to gain wide acceptance.

In a study of intraoperative acupuncture and post-tonsillectomy pain in 59 children, Tsao *et al.* found there were no significant differences in opioid dose administered in hospital or total postoperative length of stay between the control and treatment groups (6). However, the clinical trends were suggestive of improvements in the treatment group and the authors suggested the study was insufficiently powered to detect a statistical difference. Assessments following discharge, however, revealed significant improvements in postoperative pain control (P=0.0065) and earlier oral intake (P=0.01) in the acupuncture treatment group. By contrast, our larger sample study demonstrated reduced pain score in hospital, but not following discharge, in the treatment group.

Similarly, in a retrospective study of 57 children with postoperative tonsillectomy pain, Occhi found that intraoperative acupuncture significantly decreased pain for up to 72 hours after treatment (8). In separate study of 60 children, Lin *et al.* found that intraoperative acupuncture reduced pain and agitation after myringotomy (17). These studies suggest that intraoperative acupuncture may have significant benefits for up to 72 hours following treatment.

Finally, in a recent meta-analysis of 12 studies and 1,025 patients, Cho *et al.* noted that the pain score reported by patients in the first 48 postoperative hours as well as the postoperative analgesic requirements were significantly lower in the acupuncture group compared with the control group (18). No major adverse effects of perioperative acupuncture were reported in the enrolled studies. They concluded that perioperative acupuncture may provide pain relief without side effects in patients undergoing tonsillectomy. However, there were high levels of heterogeneity in several of the measured parameters, and the authors suggested that additional well-designed trials are required to further support the results of their meta-analysis.

The National Institutes of Health Consensus Statement asserts that one of the advantages of acupuncture is its substantially lower incidence of adverse effects in comparison with many drugs or other accepted procedures used to treat the same conditions (19). In this paper, the adverse effects related to acupuncture were reported in four studies. However, because the reported outcomes were different among the various studies, meta-analysis was not possible. Adverse effects included micro-hematoma, erythema or numbness at the acupuncture site, light-headedness, needle pain and discomfort caused by acupressure bandage. All these minor effects resolved quickly and spontaneously, thus demonstrating that adverse effects of acupuncture are minimal. Similarly, in our study, the only notable side-effects were minor bleeding that

either resolved spontaneously or after a few seconds with digital pressure.

We believe that it is feasible to adopt intraoperative acupuncture into routine ENT surgical practice. Our study was indeed inspired by the works of Dr. James Ochi, an ENT Specialist in San Diego, who incorporated similar acupuncture techniques into his routine adenotonsillectomy surgical procedure, after achieving his American Board certification in Medical Acupuncture and persuading his anaesthetic colleagues to do the same. While achieving accreditation and competency for acupuncture involves many years of study and practice, this particular set of acupuncture procedure for tonsillectomy is relatively straight forwards and we believe it does not require the doctors involved to master all the nuances of acupuncture to perform this safely. One particular advantage is that anaesthetists and surgeons are already familiar with the anatomy involved for needle placements and are more than capable of treating the possible uncommon complications thereof, including dizziness, nausea or bleeding. Most parents in our study appeared to be highly receptive to their children undergoing intraoperative acupuncture with only 2 out of 253 (<1%) declining to participate. The total cost of 10 Seirin acupuncture needles is about $2.00 AUD, with a box of 100 needles costing $19.95 plus delivery—a comparatively modest amount relative to the total cost of the procedure. We did not carry out a full cost-benefit analysis but, as this single treatment of intraoperative acupuncture can improve postoperative pain relief for at least 12 hours and also reduce the oxycodone requirement at home, we believe it is a highly cost-effective intervention.

Conclusions

In conclusion, the results of our study support the current literature in finding that acupuncture is an effective supplemental tool for reducing early postoperative pain and Oxycodone requirement after discharge in children following adenotonsillectomy.

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Footnote

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Supplementary

The following table provides the Criteria for the FLACC behavioural pain scale.

Behaviour	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting, back and forth, tense	Arched, rigid or jerking
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams, sobs, frequent complaints
Consolability	Content, relaxed	Reassured by touching, hugging or being talked to, distractible	Difficult to console or comfort

Instructions
Patients who are awake:
- Observe for at least 2–5 minutes.
- Observe legs and body uncovered.
- Reposition patient or observe activity; assess body for tenseness and tone.
- Initiate consoling interventions if needed.

Patients who are asleep:
- Observe for at least 5 minutes or longer.
- Observe body and legs uncovered.
- If possible reposition the patient.
- Touch the body and assess for tenseness and tone.
- Each category is scored on the 0–2 scale which results in a total score of 0–10.

Assessment of behavioural score:
- 0 = relaxed and comfortable;
- 1–3 = mild discomfort;
- 4–6 = moderate pain;
- 7–10 = severe discomfort/pain.

References: Merkel S, Voepel-Lewis T, Shayevitz JR, et al. The GLACC: A behavioural scale for scoring postoperative pain in young children. Pediatr Nurs 1997;23:293-7.

Figure S1 Face, Legs, Activity, Cry, Consolability (FLACC) pain scale.

Sample size—means.
Compare the mean of a continuous measurement in two samples:
The sample sizes are calculated in two different ways: first using the T statistic (with a non-centrality parameter), then using the Z statistic. The Z statistic approximates the T statistic, but provides sample sizes that are slightly too small. (We provide the Z statistic calculation to allow comparison with other calculators which use the Z approximation.)
Calculation:

α (two-tailed) =	0.05	Threshold probability for rejecting the null hypothesis. Type I error rate
β =	0.2	Probability of failing to reject the null hypothesis under the alternative hypothesis. Type II error rate
q1 =	0.5	Proportion of subjects that are in Group 1 (exposed)
q0 =	0.500	Proportion of subjects that are in Group 0 (unexposed); 1-q1
E =	0.35	Effect size (If μ1 = mean in Group 1 and μ0 = mean in Group 0, then E = μ1 – μ0.)
S =	1	Standard deviation of the outcome in the population

The standard normal deviate for $\alpha = Z\alpha = 1.95996$; the standard normal deviate for $\beta = Z\beta = 0.84162$; standardized effect size = (E/S) = 0.350.

(I) Calculation using the T statistic and non-centrality parameter:
N1: 129
N0: 129
Total: 258

(II) Normal approximation using the Z statistic instead of the T statistic:
A = (1/q1 + 1/q0) = 4.00000
B = ($Z\alpha$+$Z\beta$)2 = 7.84887
Total group size = N = AB/(E/S)2 = 288.296
N1: 129
N0: 128
Total: 257

This formula uses the Z statistic to approximate the T statistic. As a result, it slightly underestimates the sample size. We provide this approximation to allow comparison to other calculators that use the Z statistic.

References: Hulley SB, Cummings SR, Browner WS, et al. Designing clinical research: an epidemiologic approach. 4th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2013. Appendix 6A, page 73.
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Figure S2 Sample size calculations.