Lidocaine and phenylephrine versus saline placebo nasal spray for the pain and distress of nasogastric tube insertion in young children and infants: a randomised, double-blind, controlled trial

Simon S Craig, Robert W Seith, John A Cheek, Kathryn Wilson, Diana Egerton-Warburton, Eldho Paul, Adam West

Summary
Background Nasogastric tube insertion is a common but distressing procedure in young children. We aimed to compare the efficacy of topical local anaesthetic and vasoconstrictor nasal spray with placebo for distress related to nasogastric tube insertion.

Methods We did a prospective, randomised, controlled, double-blind, superiority trial in a single tertiary paediatric emergency department in Australia. Eligible participants were children aged 6 months to 5 years who were planned to have a nasogastric tube inserted as part of their emergency department treatment. Patients were assigned using computer-generated block randomisation to receive lidocaine and phenylephrine nasal spray (10 mg lidocaine and 1 mg phenylephrine for children weighing 6–12 kg; 20 mg lidocaine and 2 mg phenylephrine for children weighing >12 kg), or 0·9% sodium chloride placebo nasal spray, before nasogastric insertion. Guardians, observers, and proceduralists were all masked to the intervention. The primary outcome was procedure-related distress, measured using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale during the final attempt at nasogastric tube insertion. All patients were included in the primary analysis (intention-to-treat). FLACC scores were compared using the Wilcoxon rank-sum test, and categorical outcomes were compared using χ² or Fisher’s exact tests as appropriate. This study is registered with the Australian New Zealand Clinical Trials Registry, number ACTRN12614000092695.

Findings Between July 30, 2014, and Aug 17, 2017, 107 children in a convenience sample were randomly assigned to receive lidocaine and phenylephrine nasal spray (n=54) or placebo (n=53). Seven children did not receive study medication (six no longer required nasogastric tube insertion and one withdrew consent). 50 children received each intervention; all were included in the analysis. There was no difference in median FLACC score at time of nasogastric tube insertion (9 [IQR 7–10] for lidocaine and phenylephrine vs 9 [IQR 8–10] for placebo; median difference between groups −1, 95% CI −2·7 to 0·7, p=0·21). Adverse effects of the spray or nasogastric tube insertion (most commonly vomiting and gagging) occurred in 14 (28%) of those who received lidocaine and phenylephrine and 21 (42%) of those who received placebo.

Interpretation Lidocaine and phenylephrine nasal spray does not reduce procedure-related distress associated with nasogastric tube insertion in young children compared with placebo. Further research addressing distress associated with nasogastric tube insertion in young children is needed.

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interventions in adult patients involve some form of local anaesthetic administration with the use of topical nasal spray,7,9 nebulisation,10,11 or a gel.12 These techniques are all more effective than placebo; however, the relative superiority of one method over another is yet to be clearly shown. Intranasal ketamine (50 mg) was also found to be more effective than placebo in reducing the discomfort of nasogastric tube insertion in 72 adult patients.13

Only one paediatric study has been published, in 2009. Babl and colleagues14 compared nebulised lidocaine with placebo for nasogastric tube insertion in patients in a paediatric emergency department. The study was stopped early, before the intended 52 subjects had been enrolled, because of staff concern about the level of patient distress during nebulisation.

There are no studies assessing the effectiveness of a local anaesthetic nasal spray for the prevention of pain and distress associated with nasogastric tube insertion in children. Therefore, our placebo-controlled, randomised trial aimed to compare the analgesic efficacy of a proprietary preparation of lidocaine and phenylephrine nasal spray and placebo for this indication. We aimed to test the hypothesis that intranasal lidocaine and phenylephrine spray is more effective than intranasal placebo in the prevention of procedure-related distress associated with nasogastric tube insertion in children.

Methods

Study design and participants
We did a randomised, blinded, placebo-controlled, superiority trial at the emergency department of Monash Medical Centre, a tertiary referral centre in Melbourne, Australia, with an annual paediatric census of 35,000 patients. The study participants were a convenience sample. When departmental workload and staffing allowed, potential participants were screened and approached by clinical staff if they seemed to be eligible. If eligibility was confirmed and written consent obtained, participants were randomly assigned.

Randomisation and masking
We randomly assigned children to receive lidocaine and phenylephrine nasal spray or placebo, using computer-generated block randomisation with block sizes of 4. The randomisation allocation sequence and sequentially numbered bottles of study medication were prepared by the Clinical Trials Pharmacy at Monash Health, Melbourne, Australia. At randomisation, participants were allocated the next available study medication. All medications were packaged in identical containers that were stored in a locked medication room, labelled only

Added value of this study
This study is the first adequately powered study to test the utility of topical local anaesthetic and vasoconstrictor administration before nasogastric tube insertion in children aged 6 months to 5 years.

Implications of all the available evidence
Topical local anaesthetic and vasoconstrictor administration before nasogastric tube insertion had no effect on pain and distress associated with nasogastric tube insertion in children aged 6 months to 5 years. Further studies should take into account high scores for procedural pain and distress and the somewhat poor effectiveness of local anaesthetic administration alone in this population.

Evidence before this study
Nasogastric tube insertion is a painful and distressing experience for patients. Multiple studies have shown a benefit of topical or nebulised local anaesthetic before nasogastric tube insertion in adults. A review of the literature (MEDLINE and Cochrane Database of Systematic Reviews) from inception to Dec 1, 2018, using the terms “nasogastric”, “anaesthetic”, and “anesthetic” identified one study in children. This study was stopped before completion because of staff and researcher concerns regarding the level of distress that nebulisation caused. Therefore, there is little evidence to identify effective interventions to reduce the pain or distress associated with nasogastric tube insertion in children.
with the study details and the study number. The participants, guardians, treating staff, and research staff were masked to the treatment allocation. A master randomisation list was securely stored in the pharmacy and could be accessed for unmasking in an emergency.

**Procedures**

Figure 1 provides an overview of the study, indicating the timing of medication administration and data recording. Study medication, either active treatment or placebo, was administered before nasogastric tube insertion by treating clinical staff. The active medication, lidocaine and phenylephrine, was administered as a commercially available mixture of 5% lidocaine hydrochloride and 0.5% phenylephrine hydrochloride (CoPhenylcaine Forte Nasal Spray, ENT Technologies Pty Ltd, Hawthorn East, Melbourne, Australia). A preparation of 0.9% sodium chloride was used as placebo.

Medication was administered using a spray bottle and nozzle spray attachment, which provides 100 μL per spray. One spray of active medication delivers 5 mg lidocaine and 0.5 mg phenylephrine. Children weighing 6–12 kg were administered one spray to each nostril (two sprays: 10 mg lidocaine and 1 mg phenylephrine), and children weighing over 12 kg were administered two sprays to each nostril (four sprays: 20 mg lidocaine and 2 mg phenylephrine).

The doses used in the study were dictated by practical considerations such as the volume of fluid delivered by the pump nozzle of the spray bottles (100 μL) and the concentration of medication available. Also, we had to ensure that both nostrils were anaesthetised, in case insertion was difficult on one side and the other side had to be used. Therefore, we used a dose that could be delivered by one or two simple sprays, based on the maximum allowable dose by weight (3 mg/kg).

Procedure-related distress was measured using the Face, Legs, Activity, Cry and Consolability (FLACC) scale at baseline, before insertion, and during the final attempt at nasogastric tube insertion by a staff member who was not otherwise involved in the procedure. 100 mm visual analogue scale (VAS) scores for pain and distress were measured by a guardian and the staff observer. Ease of nasogastric tube insertion was recorded by the staff member doing the procedure.

**Outcomes**

The primary outcome measure was the FLACC score during the insertion of the nasogastric tube. The FLACC score is recorded between values of 0 and 10 and is calculated after scoring five observed responses (each scored between 0 and 2): facial expression, leg movement, activity, crying, and consolability.\(^6\) The score measures a composite of pain and distress in infants and young children and has previously shown to have high scores with nasogastric tube insertion.\(^9\) Secondary outcome measures included 100 mm VAS scores for pain and distress during the insertion attempts, ease of nasogastric tube insertion, number of attempts required, and procedural complications.

**Statistical analysis**

We assumed a standard deviation of the FLACC score of 2.5 on the basis of pilot data.\(^{14,17}\) With an α of 0.05 and a power of 90%, 35 patients per treatment group were required to show a 2-point difference in the FLACC score. This difference has previously been considered the minimally clinically significant difference using this scoring system.\(^{18}\) Allowing for attrition and other factors, we planned for a total of 100 patients (50 in each group).

Because the data from FLACC and VAS scores did not follow a normal distribution, we compared the scores using Wilcoxon rank-sum tests, with results reported as medians and IQRs. Categorical data, such as adverse events, were summarised as numbers (proportions) and comparisons were made using χ² or Fisher’s exact test when appropriate. All data were analysed using the intention-to-treat principle. A 2-sided p value less than 0.05 indicated statistical significance. Statistical analysis was done using Stata (version 14.2).

The trial was registered with the Australian and New Zealand Clinical Trials Registry, number ACTRN12614000092695. As the study medication was not registered in Australia for the proposed indication, the trial was also registered with the Australian Government Therapeutic Goods Administration Clinical Trials Notification Scheme, number 2014/0367, protocol number 13410A.
Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit.

Results

During the study period (July 30, 2014, to Aug 17, 2017), 180 children were assessed for study eligibility (figure 2). Because of inconsistent documentation practices within the emergency department medical records, we were unable to identify how many nasogastric tubes were inserted during this time. 107 patients were randomly assigned; however, seven patients did not receive the study medication. Six of these seven were planned to have a nasogastric tube inserted for failure of oral hydration but had recovered sufficiently to no longer require nasogastric hydration, and one patient had guardian consent withdrawn between randomisation and administration of the study medication. Data from 100 children were available for analysis.

One patient in the placebo group received inhaled nitrous oxide during the insertion of the nasogastric tube and is included in the analysis.

Baseline characteristics for both treatment groups are presented in table 1. The median weight for each group was approximately 10 kg, and the most frequent reason for nasogastric tube insertion was dehydration due to gastroenteritis. The health-care workers responsible for nasogastric tube insertion were mostly nursing staff, and their experience and confidence levels were similar in both treatment groups.

There was no difference between groups in our primary study outcome; the median FLACC score during nasogastric tube insertion was 9 (IQR 7–10) for lidocaine and phenylephrine and 9 (IQR 8–10) for placebo (p=0·21; table 2). There were no differences in FLACC scores at any other time during the study period (figure 3, table 2).

With regard to secondary outcomes, the median guardian-rated VAS score for pain was 4·5 (IQR 1·8–6·6) for lidocaine and phenylephrine and 4·5 (2·7–6·4) for placebo (p=0·72). There were no differences between groups in any other secondary outcomes relating to guardian-rated or observer-rated pain or distress (figure 4, table 2), and no difference in any incidence of complications (table 2). Results for ease of nasogastric tube insertion and number of attempts required are not available. The median VAS score for difficulty of insertion was 1·8 (IQR 0·9–4·8) for lidocaine and phenylephrine and 2·5 (0·8–5·2) for placebo. In the lidocaine and phenylephrine group, 39 nasogastric tube insertions were successful with one attempt and 45 were successful with two attempts and in the placebo group 30 were successful with one attempt and 43 were successful with two attempts.
Discussion
In this double-blind, randomised, placebo-controlled, superiority trial, we did not find evidence that the administration of a proprietary lidocaine and phenylephrine nasal spray to children aged 6 months to 5 years reduced FLACC scores associated with nasogastric tube insertion compared with placebo. We were also unable to find any differences between the treatment groups in any secondary outcomes relating to observer or guardian ratings of pain and distress, or complications.

Nasogastric tube insertion is a painful and distressing experience for patients. Multiple studies have shown a benefit of topical or nebulised local anaesthetic before nasogastric tube insertion in adults,7,9,11 and only one study in children.14 This study was stopped before completion because of staff and researcher concerns regarding the level of distress that nebulisation caused. Therefore, there is little evidence to identify effective interventions to reduce the pain and distress associated with nasogastric tube insertion in children. This study is the first adequately powered study to test the utility of topical local anaesthetic before nasogastric tube insertion in children aged 6 months to 5 years of age. The high FLACC scores obtained during nasogastric tube insertion are consistent with Babl and colleagues’ study of nebulised lidocaine14 and confirm the unpleasant nature of the procedure. Neither our study of topical lidocaine and phenylephrine spray nor Babl and colleagues’ study was able to show a benefit of the administration of topical local anaesthetic for nasogastric tube insertion in young children. This finding contrasts with multiple adult studies showing a useful effect of local anaesthetic, regardless of whether it is administered by nebuliser,10,11 topical spray,13,14 or gel.15 Interestingly, a similar phenomenon has been described in relation to the administration of topical local anaesthetic for urethral catheterisation in young children. Neither a 2017 meta-analysis19 nor a more recent randomised clinical trial20 showed any reduction in procedural pain scores with the use of local anaesthetic for this indication. This finding contrasts with results from adult studies, which show a clear benefit in male21 and female22 patients.

Whether the differences in local anaesthetic efficacy for painful procedures in adults compared with children are a result of differences in measurement methods, or differences in anaesthetic effect is unclear. Self-reported pain scores used in adults might differ in their measure of pain or distress in children, as some were in our study, and there is evidence for painful procedures in adults compared with children. Whether the differences in local anaesthetic efficacy for painful procedures in adults compared with children are a result of differences in measurement methods, or differences in anaesthetic effect is unclear. Self-reported pain scores used in adults might differ in their measure of pain or distress in children, as some were in our study, and there is evidence that pain thresholds are lower in children compared with adults.23 While pain thresholds may differ between adults and children, self-reported pain may not differ. The FLACC score is a measure of procedural discomfort, and may be a reliable measure of pain or distress in children.24 In this study, FLACC scores in children were consistent with FLACC scores in adults,7,9,11 and only one study in children.14 This study was stopped before completion because of staff and researcher concerns regarding the level of distress that nebulisation caused. Therefore, there is little evidence to identify effective interventions to reduce the pain and distress associated with nasogastric tube insertion in children. This study is the first adequately powered study to test the utility of topical local anaesthetic before nasogastric tube insertion in children aged 6 months to 5 years of age. The high FLACC scores obtained during nasogastric tube insertion are consistent with Babl and colleagues’ study of nebulised lidocaine14 and confirm the unpleasant nature of the procedure. Neither our study of topical lidocaine and phenylephrine spray nor Babl and colleagues’ study was able to show a benefit of the administration of topical local anaesthetic for nasogastric tube insertion in young children. This finding contrasts with multiple adult studies showing a useful effect of local anaesthetic, regardless of whether it is administered by nebuliser,10,11 topical spray,13,14 or gel.15 Interestingly, a similar phenomenon has been described in relation to the administration of topical local anaesthetic for urethral catheterisation in young children. Neither a 2017 meta-analysis19 nor a more recent randomised clinical trial20 showed any reduction in procedural pain scores with the use of local anaesthetic for this indication. This finding contrasts with results from adult studies, which show a clear benefit in male21 and female22 patients.

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Table 2: Observer-rated FLACC scores, pain, distress, and complications

<table>
<thead>
<tr>
<th>FLACC score</th>
<th>Lignocaine and phenylephrine (n=50)</th>
<th>Placebo (n=50)</th>
<th>Difference in medians (95% CI)</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0 (0 to 2)</td>
<td>1 (0 to 4)</td>
<td>-1 (-2.5 to 0.5)</td>
<td>0.12</td>
</tr>
<tr>
<td>Pre-procedure</td>
<td>3 (1 to 6)</td>
<td>5 (2 to 7)</td>
<td>-1 (-2.7 to 0.7)</td>
<td>0.21</td>
</tr>
<tr>
<td>During procedure</td>
<td>9 (7 to 10)</td>
<td>9 (8 to 10)</td>
<td>0 (-1.1 to 1.1)</td>
<td>0.21</td>
</tr>
<tr>
<td>Post-procedure</td>
<td>2 (0 to 4)</td>
<td>3 (1 to 5)</td>
<td>-1 (-2.6 to 0.6)</td>
<td>0.25</td>
</tr>
<tr>
<td>Observer-rated distress (VAS)</td>
<td>7.15 (5.0 to 8.1)</td>
<td>7.55 (6.4 to 9.3)</td>
<td>-0.39 (-1.4 to 0.6)</td>
<td>0.72</td>
</tr>
<tr>
<td>Observer-rated pain (VAS)</td>
<td>3.8 (2.0 to 5.0)</td>
<td>3.3 (2.0 to 4.8)</td>
<td>0.5 (-1.0 to 2.0)</td>
<td>0.45</td>
</tr>
<tr>
<td>Guardian-rated distress (VAS)</td>
<td>6.9 (5.5 to 8.0)</td>
<td>7.65 (4.5 to 9.3)</td>
<td>-0.75 (-2.3 to 0.8)</td>
<td>0.93</td>
</tr>
<tr>
<td>Guardian-rated pain (VAS)</td>
<td>4.5 (1.8 to 6.5)</td>
<td>4.45 (2.65 to 6.4)</td>
<td>0.04 (-2.0 to 2.1)</td>
<td>0.08</td>
</tr>
<tr>
<td>Any complication</td>
<td>14 (28%)</td>
<td>21 (42%)</td>
<td>2 (-2.0 to 2.0)</td>
<td>1.00</td>
</tr>
<tr>
<td>Spray complication</td>
<td>4 (8%)</td>
<td>3 (6%)</td>
<td>1 (0 to 4)</td>
<td>0.25</td>
</tr>
<tr>
<td>Any nasogastric tube insertion complication</td>
<td>14 (28%)</td>
<td>19 (38%)</td>
<td>-5 (1.0 to 3.0)</td>
<td>0.29</td>
</tr>
<tr>
<td>Bleeding</td>
<td>1 (2%)</td>
<td>4 (8%)</td>
<td>-3 (0 to 4)</td>
<td>1.00</td>
</tr>
<tr>
<td>Vomiting, gagging, or retching</td>
<td>6 (12%)</td>
<td>6 (12%)</td>
<td>0 (0 to 2)</td>
<td>0.12</td>
</tr>
<tr>
<td>Bleeding and vomiting</td>
<td>1 (2%)</td>
<td>4 (8%)</td>
<td>-3 (0 to 4)</td>
<td>1.00</td>
</tr>
<tr>
<td>Dislodgement</td>
<td>4 (8%)</td>
<td>3 (6%)</td>
<td>1 (0 to 4)</td>
<td>0.12</td>
</tr>
<tr>
<td>Dislocation</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
<td>1 (0 to 4)</td>
<td>0.12</td>
</tr>
<tr>
<td>Other</td>
<td>2 (4%)</td>
<td>1 (2%)</td>
<td>1 (0 to 4)</td>
<td>0.12</td>
</tr>
</tbody>
</table>

Data are median (IQR) or n (%). FLACC=Face, Legs, Activity, Cry and Consolability. VAS=visual analogue scale. *All p values calculated by Wilcoxon rank-sum test unless otherwise specified. †χ² test. ‡One dislodged nozzle and one irritation and mucus. §One bleeding, one discomfort, one unsuccessful on one side ¶Fisher’s exact test. ‖Coughing (two episodes). **Not specified (one episode).
including pain, fear, unfamiliar surroundings, immobilisation, or the unpleasant sensation of having a plastic tube inserted. Notably, FLACC scores were high pre-procedure, the point immediately before nasogastric tube insertion (figure 1), which was after the spray had been given and while the child was being positioned before nasogastric insertion, but before any attempts at nasogastric insertion were made. Presumably, the high scores at this point reflect distress not related to pain.

There are several limitations to this study. We used convenience sampling, which was dependent on departmental workload and availability of clinical staff to assist with recruitment and data collection. This method might have resulted in spectrum bias, reducing the number of unwell children enrolled and therefore reducing the opportunity to show a difference. Another limitation is the administration of the study medication by emergency department nurses rather than research staff. Although training was provided and study investigators were available to help if required, there might have been incorrect use of the nasal spray device. The randomisation process would be expected to reduce any effect of incorrect use.

The use of the FLACC score in our study is a potential limitation. In particular, many children in each treatment group had the maximum score recorded, suggesting an inability to discriminate at the higher end of the scale. However, there is no gold standard for the assessment of procedural pain and distress in young children. At the time of the study protocol development (2012–13), FLACC was the best validated tool available, and was used in most studies of procedural pain and distress. Since then, further studies, particularly those done by Crellin and colleagues, have shown that the FLACC score is reliable and sensitive to pain for procedural pain assessment, although how well the scale differentiates pain-related and non-pain-related distress is unclear. The Modified Behavioural Pain Scale is an alternative measure; however, similar concerns relating to pain-related and non-pain-related distress have been raised, along with feasibility and appropriateness of item descriptors.

We did not allocate a standard time for the spray to work. However, the practicalities of moving a child (and guardian) from one room to the procedure room, positioning them on the bed and ensuring staff and equipment were assembled for the procedure reflect the clinical environment, and realistically take a minimum of 2–3 min.

The recording of observational pain scales (such as the FLACC score) by clinical staff, although a routine part of nursing care in our department, might be viewed as another potential limitation. Despite these concerns, and the use of a single staff member (rather than two observers to assess interrater reliability), this real-world setting increases external validity, and numerous similar studies of procedural pain in young children have applied the FLACC score. Nursing staff undergo regular training on various aspects of paediatric care. Pain assessment, including the use of the FLACC, is an important part of training for the care of infants and young children. This routine training was supplemented by additional training for the study. Additionally, the high scores for guardian and observer ratings of pain and distress using the VAS (and no differences between the treatment groups) were consistent with the observational FLACC scores.

We acknowledge that multiple tests were done, which increases the chance that a statistically significant finding will occur in the absence of a difference actually existing. To allow for this, we should have set a lower threshold for statistical significance using a multiple comparison test (eg, Bonferroni method). However, given that none of our results even approached statistical significance at a p value of less than 0·05 (ie, there was no difference between treatment groups), we do not feel that correction in this way was necessary.

Further studies assessing interventions for procedure-related distress associated with nasogastric tube insertion in young children should take into account the somewhat poor efficacy of local anaesthetic administration alone in this population. Interventions with an anxiolytic or amnestic effect, such as midazolam or nitrous oxide, appear to be effective for various painful paediatric procedures and are therefore a promising direction for future research either alone or as an adjunct to local anaesthetic.

In conclusion, we found that lidocaine and phenylephrine nasal spray is not superior to saline placebo in reducing the procedure-related distress associated with nasogastric tube insertion in infants and young children.
Contributors

SSC and DE-W were responsible for identifying the research question. SSC was responsible for the study design and research protocol, and for drafting the article. RWS, JAC, and DE-W contributed to the study design and development of the protocol. SSC, RWS, JAC, AW, and KW collected the data. SSC and EP were responsible for the statistical analysis. All authors provided comments on the drafts and have read and approved the final version of the Article. All authors had full access to all the data (including statistical reports and tables) at the conclusion of the study and take responsibility for the integrity of the data and the accuracy of the data analysis. SSC takes responsibility for the paper as a whole.

Declaration of interests

We declare no competing interests.

Data sharing

Deidentified participant data, including individual participant data and a data dictionary defining each field in the set, will be made available to researchers by all authors and can be submitted by emailing Prof Simon Craig (simon.craig@monash.edu).

Acknowledgments

We would like to acknowledge funding support for this project from the National Health and Medical Research Council, Australia; the Australian National Health and Medical Research Council, Australia; and the Australian Research Council, Australia. We acknowledge the participating families and health professionals who contributed to the project, and Dr Andrew Cullen, Professor of Anaesthesia, for his invaluable advice and support. We would also like to acknowledge people at the Monash Children’s Hospital, Australia; the Children’s Hospital at Westmead, Australia; and the Northern Sydney Local Health District, Australia, for their support.

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