

# Should lidocaine spray be used to ease nasogastric tube insertion? A double-blind, randomised controlled trial

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- Objective** To investigate the efficacy and safety of lidocaine nasal spray before nasogastric tube insertion in an emergency department.
- Design** Double-blind, randomised controlled study.
- Setting** Emergency department of a major regional hospital in Hong Kong.
- Patients** A total of 206 adult patients, for whom nasogastric tube insertion was indicated.
- Main outcome measures** Primary outcome was discomfort gauged on a visual analogue scale, and Likert scale addressing difficulty of nasogastric tube insertion.
- Results** Compared with placebo spray use, lidocaine spray use was associated with less patient discomfort, and less difficulty in nasogastric tube insertion, both difference being statistically significant.
- Conclusion** Intranasal lidocaine spray before nasogastric tube insertion was safe and effective in reducing patient discomfort related to the procedure.

## Introduction

Nasogastric (NG) tube insertion is commonly performed in the accident and emergency department (AED). It is an unpleasant procedure with risks.<sup>1</sup> Moreover there is no consensus or guideline for using analgesia to facilitate insertion. Emergency physicians are often reluctant to use procedural anaesthesia before NG insertion.<sup>2</sup> Studies showed that there was a more-than-20% rate of unsuccessful NG tube insertion in the absence of any anaesthesia, and more than 5% of patients have inadequate pain control, and complications arise in more than 10% of them.<sup>3-5</sup>

To date, in Hong Kong there have been no large-scale, prospective, randomised studies to investigate the efficacy of lidocaine sprays for NG tube insertion. In western countries, studies have shown the benefits of local anaesthesia (in various forms) over lubricant jelly alone when used for this purpose.<sup>6</sup> Such treatment, however, was rarely used in local settings, whether due to inconvenience or unavailability. Many of the studies entailed only small samples (<50),<sup>7</sup> and not all were standardised, randomised, or double-blind. One of the studies involving lidocaine jelly before NG tube insertion was inconclusive,<sup>8</sup> and others mostly entailing nebulised lidocaine did not show much benefit for patients.<sup>9,10</sup>

The aim of this study was to assess the efficacy and safety of lidocaine spray prior to NG tube insertion. We hypothesised that using lidocaine spray before NG tube insertion can decrease patient discomfort and improve the success rate, and result in fewer adverse effects from the procedure.

## Methods

This study was conducted in the AED of the Queen Elizabeth Hospital (QEH). The AED in QEH received about 200 000 new patients per annum, 20% of whom were admitted. Ethical approval was received from the Kowloon Central Cluster Ethics Committee to conduct a pragmatic, prospective, double-blind, randomised controlled study to compare the efficacy of lidocaine nasal spray (Xylocaine; AstraZeneca, Hong Kong SAR, China) used prior to NG tube insertion. Informed written consent was obtained from each patient.

### Key words

Anesthetics, local; Intubation, gastrointestinal; Lidocaine; Lubrication; Pain measurement

*Hong Kong Med J* 2010;16:282-6

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### Inclusion criteria and exclusion criteria

All patients aged 18 years or more presenting to the A&E with any condition deemed requiring NG tube insertion for either intestinal obstruction or upper gastro-intestinal bleeding were considered. All patients were studied on an intention-to-treat basis. Patients were excluded if they endured major trauma, facial trauma, or fractured base of the skull. Additional patient exclusion criteria were: assessment of pain not being feasible, systolic blood pressure of lower than 100 mm Hg, allergy to lidocaine, impaired gag reflex, reactive airway disease, pregnancy, or lactation.

### Sample size calculation

In all, at least 48 patients were to be recruited (power=0.8, alpha=0.05). This sample size calculation was based on the study by Wolfe et al<sup>11</sup>; 24 patients being required in each of the treatment arms (lidocaine spray and placebo) to show a statistically significant difference of 20 mm in visual analogue scale (VAS) scores (estimated standard deviation 25 mm, power 0.8, alpha=0.05 [2-tailed]). This difference was based on a study by Kelly et al,<sup>12</sup> suggesting that a difference in VAS score of less than 20 mm was unlikely to be clinically meaningful.

### Randomisation, interventions, and preparation of medication

An independent researcher first used a computer program (Um Block Randomization Program) to pre-assign consecutive patients to either placebo or active treatment groups, in blocks of predetermined size. Random treatment assignments, either card A (use medication A) or card B (use medication B), were placed in sealed, opaque, and tamper-proof envelopes. After the patient was recruited, a research nurse opened a pre-coded envelope which contained a card inside, either card A or card B. Patients were then assigned to receive medication A or medication B before NG tube insertion. Medication A or B could be either lidocaine spray or normal saline. The researcher in-charge changed the sequence every day. All of the clinicians and nurses on duty, the research nurse, and the patients were blinded to the medications.

### Standardisation

We standardised the materials used: the trial medications were either 10% lidocaine solution or normal saline (placebo), and only 16-French size of NG tubes were inserted after lubrication with 1 mL of KY jelly (Johnson & Johnson, US). The procedure was also standardised and entailed: one spray (1 mL) to each nostril, two sprays (2 mL) to the throat, and

## 一項探討置鼻胃管時應否使用lidocaine噴霧劑的雙盲隨機對照研究

目的	探討在急症室內為病人置鼻胃管前使用lidocaine噴霧劑的效用及安全性。
設計	雙盲隨機對照研究。
安排	香港一所主要分區醫院的急症部門。
患者	共206位須置鼻胃管的成年病人。
主要結果測量	病人按視覺類比量表評估置管的不適度，及醫護人員按李克特量表得出的置管難度。
結果	與安慰劑對照組比較，使用lidocaine噴霧劑能顯著減少病人的不適，而醫護人員置入鼻胃管的難度也較低。
結論	置鼻胃管前於鼻內使用lidocaine噴霧劑不但安全，而且可以有效減低病人不適的感覺。

no repeat spray. The NG tube insertion was only to be undertaken 5 minutes after spraying of the trial agents.

### Data collection: scores, durations, vitals, and symptoms

After NG tube insertion, patients were asked to mark respective discomfort scores on a VAS, which was a 10-cm line extending from 'no discomfort' to 'severe discomfort', marked on each end. Difficulty inserting the NG tube was recorded on a Likert scale by the relevant nurse. The scale contained 5 points of difficulty: 'minimal', 'slight', 'moderate', 'substantial', and 'extreme'. Rating of insertion from start to end, number of attempts, final success or failure of insertion, complications, and patient vital signs (blood pressure, pulse, and oxygen saturation) before and after insertion were also recorded.

### Clinical outcome

Primary clinical outcomes were the discomfort score and the difficulty in inserting the NG tube after use of the spray. Secondary outcomes were the duration of the insertion procedure, number of attempts, and success or failure. In this context, the need for two or more attempts at insertion was regarded as "failed insertion". Any adverse events were also recorded.

### Statistical analysis

Data were analysed on an intention-to-treat basis and all statistical tests were two-tailed tests. Comparison of the mean change in VAS discomfort score and the Likert scale were analysed by analysis of covariance. Baseline characteristics of categorical

TABLE 1. Patient demographic characteristics

Characteristic*	Lidocaine group	Placebo group	P value	95% Confidence interval for difference between two groups
Mean age (years)	60	60	0.922 <sup>†</sup>	-10 to 3
Sex (M:F)	75%:25%	57%:43%	0.577 <sup>†</sup>	-12 to 7
Indication (GIB, IO)	GIB=68%, IO=32%	GIB=69%, IO=31%	0.882 <sup>‡</sup>	-4 to 8
Co-morbid illness	53%	57%	0.577 <sup>‡</sup>	-6 to 9
SBP (mm Hg)	137	140	0.393 <sup>§</sup>	-3 to 12
Mean DBP (mm Hg)	76	78	0.530 <sup>§</sup>	-9 to 10
Mean pulse rate (beats/min)	90	88	0.505 <sup>§</sup>	-5 to 18
Mean BP (mm Hg)	107	109	0.380 <sup>§</sup>	-2 to 9
Mean SaO <sub>2</sub> (%)	98	98	0.295 <sup>§</sup>	-7 to 12

\* GIB denotes gastro-intestinal bleeding, IO intestinal bleeding, SBP systolic blood pressure, DBP diastolic blood pressure, BP blood pressure, and SaO<sub>2</sub> arterial oxygen percent saturation

<sup>†</sup> One-way analysis of variance

<sup>‡</sup> Chi squared test

<sup>§</sup> Kruskal-Wallis test

TABLE 2. Outcome vitals

Outcome* <sup>†</sup>	Lidocaine group	Placebo group	P value (Kruskal-Wallis test)	95% Confidence interval for difference between two groups
Post-SBP (mm Hg)	141	148	0.043	2 to 9
Post-DBP (mm Hg)	79	84	0.021	-4 to -1
Post-pulse rate (per min)	91	92	0.851	-8 to -2
Post-BP (mm Hg)	110	116	0.016	5 to 12
Post-SaO <sub>2</sub> (%)	98	98	0.946	-3 to -2

\* SBP denotes systolic blood pressure, DBP diastolic blood pressure, BP blood pressure, and SaO<sub>2</sub> arterial oxygen percent saturation

<sup>†</sup> All are in mean values

data were compared using Chi squared or Fisher's exact tests. One-way analysis of variance was used to compare continuous data that conformed to normal distributions, whilst the Kruskal-Wallis test was used for timed data that did not fit a normal distribution.

## Results

Between 30 May 2005 and 20 October 2005, 224 patients were recruited. Six patients withdrew from the study. Twelve patient records were discarded due to incomplete data. A total of 206 patients were therefore randomised—103 were allocated to active treatment (lidocaine), and 103 to receive placebo.

### Baseline characteristics

Baseline characteristics of both active and placebo group patients were similar (Table 1).

### Effects on vital signs/functions

The systolic blood pressure, diastolic blood pressure, mean blood pressure, pulse, and oxygen saturation for the treatment and placebo groups showed statistically significant differences (Table 2).

### Clinical outcome measures

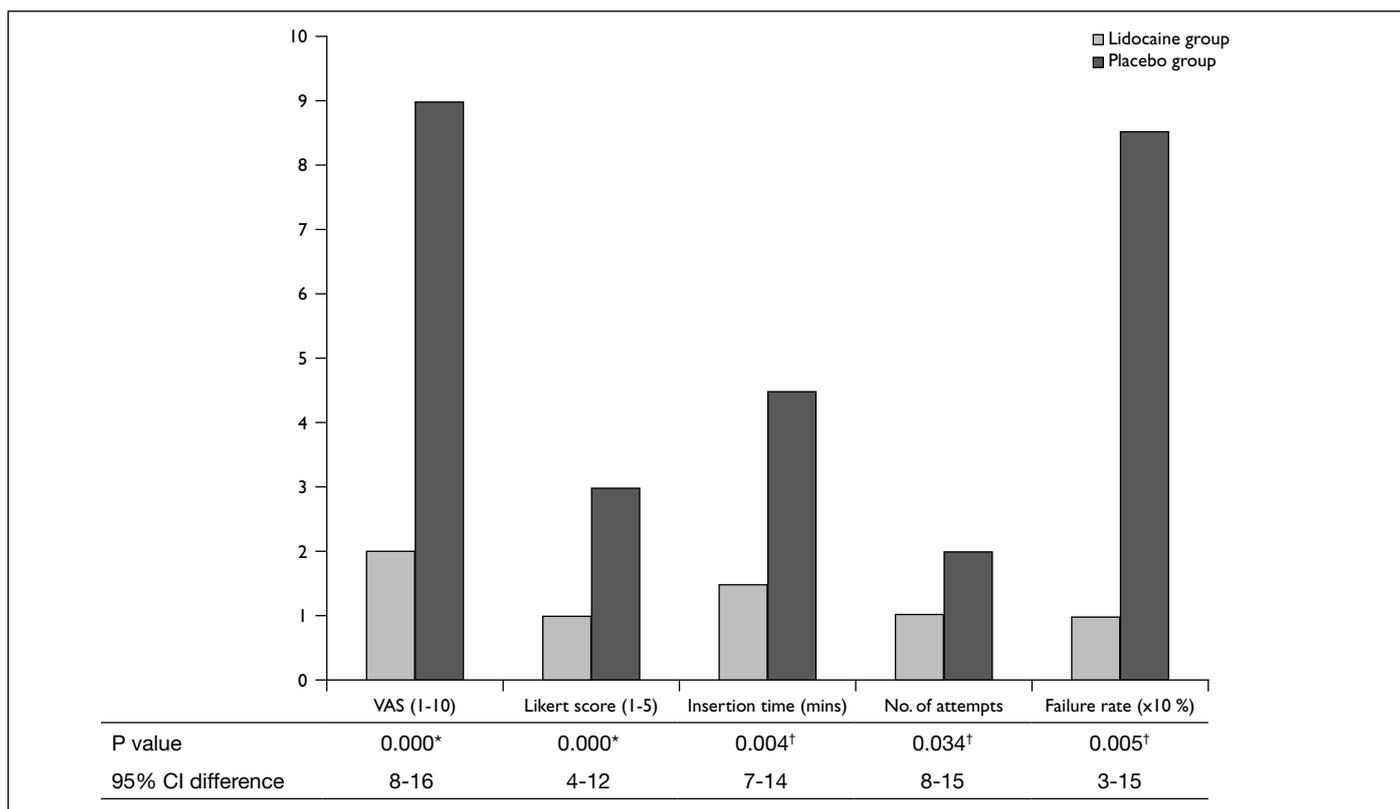
The mean VAS discomfort scores in the treatment group was 2, whereas that in placebo group was 9 (P<0.005). The mean Likert score in active treatment group was 1 (minimal difficulty) but in the placebo group it was 3 (moderate difficulty) [P<0.005]. The mean NG insertion time was 1.5 minutes in the active treatment group and was 4.5 minutes in the placebo group (P<0.005). In the active treatment group, on average only one attempt was necessary, but on average two attempts were needed to pass the NG tube in the placebo group (P<0.005). The percentage of failed insertions was 10% in the active treatment group and 85% in the placebo group (P<0.05) [Fig].

### Adverse effects

Patients in the placebo group experienced many more adverse effects than those in the active treatment group. Moreover, for most of the adverse effects listed in Table 3, the differences in the proportions of patients in the two groups were statistically significant.

## Discussion

This study showed that patients receiving lidocaine as



\* Analysis of covariance

† Kruskal-Wallis test

FIG. Outcome measures

VAS denotes visual analogue scale score, and CI confidence interval

TABLE 3. Adverse effects

Adverse effect	Lidocaine group	Placebo group	P value*	95% confidence interval for difference between two groups
Cough	8%	19%	0.015	3 to 8
Vomit	4%	65%	<0.001	4 to 9
Epistaxis	2%	12%	0.017	7 to 16
Chest pain	0%	12%	0.002	3 to 18
Dizziness	0%	12%	0.002	6 to 14
Shortness of breath	1%	41%	<0.001	5 to 10
Epigastric pain	0%	10%	0.001	7 to 13
Face petechiae	0%	6%	0.013	2 to 18
Palpitation	1%	4%	0.36	-2 to 9
Numbness	0%	0%	<0.001	7 to 20
Allergy	0%	0%	<0.001	5 to 18
Tracheal insert	0%	0%	<0.001	6 to 13

\* Analysis of covariance

opposed to placebo spray prior to NG tube insertion experienced much less discomfort during the process; the respective average VAS discomfort scores were 2 versus 9. Difficulty inserting an NG tube was rated as moderate if placebo spray was used, but minimal if lidocaine spray was used. If lidocaine spray was used, the average NG tube insertion time was 3 minutes

shorter than after placebo use. The corresponding success rates for insertion were 90% and 15%, which were also in keeping with reports from other studies.<sup>3-5</sup> The reasons could be that patients not receiving lidocaine spray before tube insertion suffered more from: coughs (by 11%, P<0.05), vomiting (by 61%, P<0.05), epistaxis (by 10%, P<0.05), chest pain (by

12%,  $P<0.05$ ), dizziness (by 12%,  $P<0.05$ ), shortness of breath (by 40%,  $P<0.05$ ), epigastric pain (by 10%,  $P<0.05$ ), and facial petechiae (by 6%,  $P<0.05$ ). These adverse effects could all have interacted to produce a much higher failure rate in the placebo group. The cost of lidocaine spray is small (about HK\$1 per spray in a 50 mL bottle). Thus, the cost-effectiveness of the local anaesthetic was clearly demonstrated, and should convince emergency physicians to change their practice and use such treatment more regularly before NG tube insertion.

### Strengths and weaknesses of the study

The strength of our study lies in its double-blind, randomised controlled design, that enable the efficacy and safety of the lidocaine spray use before NG tube insertion to be properly assessed. However, it was not possible to have independent staff to record outcomes, as blinding may not have been adequate; the smell and taste of the placebo was not identical to that of lidocaine. Staff and patients

may therefore have identified the spray treatments involved. Moreover, there was no assessment of post-procedural blinding by an independent member of staff. Another weakness was that elderly patients (who are more prone to endure NG tube dislodgement) were not included in our study. The generalisability of this study may therefore have been affected.

### Conclusion

Lidocaine spray before NG tube insertion significantly reduced patient discomfort. The procedure's difficulty, duration, and number of insertion attempts were all reduced. Actively treated patients also suffered far fewer adverse effects from NG tube insertion. Thus, the use of lidocaine spray before NG tube insertion should be more widely advocated and adopted.

### Declaration

No conflicts of interest were declared by the authors.

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