Comparison of the Efficacy between Lidocaine Spray plus Lidocaine Jelly Lubrication and Lidocaine Jelly Lubrication Alone Prior to Nasogastric Intubation: A Prospective Double-Blind Randomized Controlled Study

Supot Pongprasobchai MD*, Thanjira Jiranantakan MD*,
Akarin Nimmannit MD**, Cherdchai Nopmaneejumruslers MD*

*Department of Medicine, Faculty of Medicine, Siriraj Hospital, Bangkok
** Office for Research and Development, Faculty of Medicine, Siriraj Hospital, Bangkok

Objective : *Although a common procedure, nasogastric (NG) intubation is also painful and unsatisfactory. Previous studies showed the benefits of local anesthesia in various forms over lubricant jelly alone, but they are rarely used due to their inconvenience and unavailability. The authors conducted a double-blind randomized controlled study to compare a commercial-available 10% lidocaine spray plus 2% lidocaine jelly lubrication and 2% lidocaine jelly lubrication alone prior to NG intubation.*

Material and Method : *Patients who fulfilled the indications for NG intubation were randomized to receive either 10% lidocaine spray or placebo (normal saline) spray to the nostril and throat prior to NG intubation. NG tubes lubricated with 2% lidocaine jelly were then inserted by experienced physicians. Physician, who sprayed, inserted the NG tubes and collected the patient's data, did not know the content of the spray, while patients were also blinded against the information of the spray.*

Results : *Sixty patients were included in the present study. Thirty one randomly received lidocaine spray and 29 received placebo spray. There were more female patients in the lidocaine group (65% vs. 28%, $p = 0.04$), but ages, indications for NG intubation, size of NG tube, and physicians' experience in the procedure were similar in both groups. Patients' discomfort after being sprayed was also similar in both groups. However, during the NG intubation, the patients in the lidocaine group experienced less pain as measured by visual analog scale (23.6 ± 16.6 vs. 43.1 ± 31.4 mm, $p = 0.005$) and less discomfort (30.0 ± 24.4 vs. 51.4 ± 30.0 mm, $p = 0.004$) than the placebo group. Ninety-three percent of the patients in the lidocaine group favored the same spray for their next intubations, while 65% of the placebo group did ($p = 0.009$). In addition, there was more physicians' satisfaction in the lidocaine group as measured by 5-point Likert scale ($p = 0.041$). Likewise, 61% of the physicians favored lidocaine spray compared to 34.5% of the placebo spray ($p = 0.038$). Degree of difficulty, duration of intubation, number of attempts and success rates of NG intubations were as well similar in both groups. No complications were found in the present study.*

Conclusion : *10% lidocaine spray plus 2% lidocaine jelly lubrication was more effective in relieving patients' pain, discomfort, and resulted in higher physicians' satisfaction. There were also no additional side effects as compared to 2% lidocaine jelly lubrication alone. Therefore, it should be recommended for routine application.*

Keywords *: Nasogastric tube, Nasogastric tube insertion, Nasogastric intubation, Lidocaine spray, Lidocaine jelly, Anesthesia, Pain, Discomfort*

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Correspondence to : Pongprasobchai S, Division of Gastroenterology, Department of Internal Medicine, Faculty of Medicine, Siriraj Hospital, Bangkok 10700, Thailand. Phone: 0-2419-7281, Fax: 0-2411-5013, E-mail: supotpong@hotmail.com

Nasogastric (NG) intubation is a common medical procedure in clinical practice but it can also be painful and unsatisfactory to the patients. There have been studies demonstrating the benefits of various forms of local anesthesia including jelly form, spray, atomized spray and nebulizer over lubricant jelly alone in relieving patient's pain and discomfort during NG intubation[1-7]. Recently, some strategies other than local anesthesia were also studied and showed positive results, such as intravenous metoclopramide and behavioral patterns of comforting care[8-9].

Despite the proven benefits of using local anesthesia prior to NG intubation, they are rarely used in routine practice. From a survey of residents and attending emergency physicians working in one tertiary care medical center[10], 98% believed that NG intubation caused pain and discomfort to patients. Thirty-seven percent accepted that they inadequately applied pain control and only 24% actually used strategies that they thought to be the most effective procedure. Similarly, a survey of the Internal Medicine residents in Siriraj Hospital showed that 88% used only lidocaine lubrication jelly and 50% still used lubrication jelly alone without lidocaine. Majority of them believed that lidocaine spray could be the most practical anesthetic method.

For these reasons, the authors believe that the availability and the easy-to-use form of local anesthesia should probably be the most important factors to determine the increasing use of local anesthesia prior NG intubation by physicians. Currently, 10% lidocaine spray and 2% lidocaine jelly are the 2 forms of local anesthesia mostly available in Thailand. However, no study has tested the efficacy of these 2 options for facilitating NG intubation. Furthermore, some ethnics may have different pain threshold from another. The authors would like to know whether the use of local anesthesia prior to NG intubation has similar efficacy in Thai patients. Thus, the authors conducted a prospective double-blind randomized controlled study to compare the efficacy between the two commercial-available forms (the 10% lidocaine spray plus 2% lidocaine jelly lubrication and the 2% lidocaine jelly lubrication alone) of local anesthesia prior to the NG intubation in relieving patients' pain and discomfort.

Material and Method

Study design and population

The present study was a prospective double-blind randomized controlled trial in outpatients and inpatients of the Department of Internal Medicine, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand between October and December 2006.

All patients who were more than 18 years old and indicated for NG intubation were eligible for enrollment. Exclusion criteria were the inability to answer questions (e.g. alteration of consciousness, language problems), the anatomical defects in the ear, nose or throat regions that might cause difficulty in NG intubation, signs and symptoms of coagulopathy, history of lidocaine allergy and patients with unstable

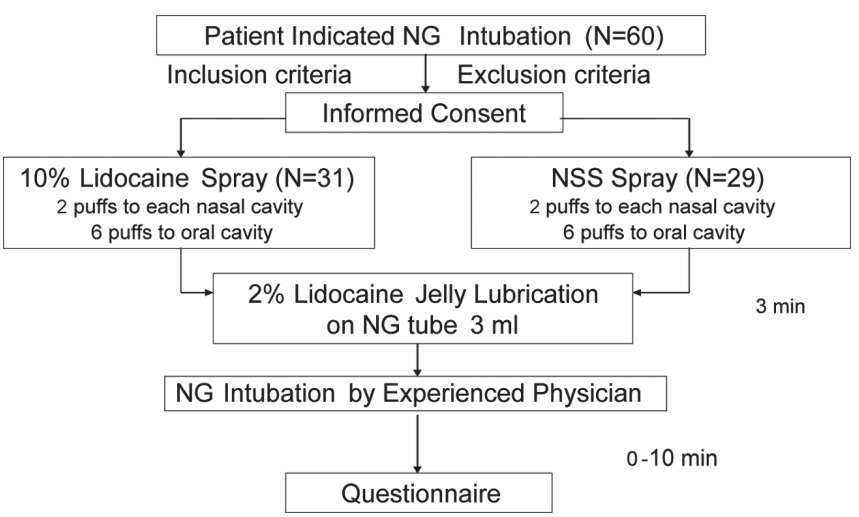

Fig. 1 Study protocol

Table 1. Patients' demographic data

Characteristics	Type of spray		p
	Lidocaine (n = 31)	Placebo (n = 29)	
Gender, n (%)			
Male	11 (35.5)	21 (72.4)	0.040
Female	20 (64.5)	8 (27.6)	
Age (year)			
mean ± SD	55 ± 16.4	55 ± 16.2	0.989
(range)	(21-86)	(24-86)	
Indication for NG intubation, n (%)			
GI bleeding	19 (61.3)	17 (58.6)	0.459
Gut obstruction	7 (22.6)	5 (17.2)	
Feeding	5 (16.1)	7 (24.1)	
Setting, n (%)			
Outpatient	26 (83.9)	25 (86.2)	1.000
Inpatient	5 (16.1)	4 (13.8)	
Size of NG tube, n (%)			
14F	5 (16.1)	7 (24.1)	0.438
18F	26 (83.9)	22 (75.9)	
Patient's experience on NG intubation, n (%)			
First	20 (64.5)	20 (69.0)	0.715
Second or more	11 (35.5)	9 (31.0)	
Physician who inserted NG tube, n (%)			
1st year resident	28 (90.3)	27 (93.1)	1.000
2nd year resident	3 (9.7)	2 (6.9)	
Patient's experience with lidocaine spray prior to NG intubation, n (%)			
No	31 (100)	29 (100)	1.000
Physician's experience with lidocaine spray prior to NG intubation, n (%)			
Yes	30 (96.8)	29 (100)	1.000
No	1 (3.2)	0 (0)	

hemodynamics (systolic blood pressure < 90 mmHg, pulse rate > 120/min, respiratory rate > 30/min). Intoxicated patients were also excluded.

Sample size was calculated basing on the study by Wolfe et al[1]. Twenty five patients were required in each group for the statistically significant difference in patient's pain of 20 mm apart by visual analog scale (power 0.8, $\alpha = 0.05$ [2-tailed]).

Process and interventions

Diagram of the study protocol is shown in Fig. 1. After informed consent, all eligible patients were randomized by the block-of-4 method and stratified by the size of NG tubes. Patients, whose indications were for feeding, were inserted with the 14F NG tube, while those whose indications were gut obstruction or gastrointestinal hemorrhage were intubated with the 18F NG tube.

Patients, who were randomized to the treatment group, received 10% lidocaine spray, and those in placebo group received normal saline solution (NSS) spray. Both solutions were identical in appearance as clear liquid solutions, packaged in identical spraying devices labeled as "Solution A" and "Solution B" by one of the investigator who was not involved in another study process. Single investigator (T.J.) was responsible for spraying these solutions to the patients and collected all the data in every patient throughout the present study. As a result, the physician who sprayed and collected data, the physicians who inserted the NG tubes and the patients, were all blinded for the types of spray used.

Every patient was sprayed with 2 puffs of either 10% lidocaine or NSS (according to the group they were assigned) to each nostril and 6 puffs to the throat (equivalent to a total of 140 mg or 1.4 ml of 10%

lidocaine and 1.4 ml of NSS, respectively). After waiting for 3 minutes for full anesthetic effect[11], patients were inserted with NG tube lubricated with 3 ml of 2% lidocaine jelly by Internal Medicine or Emergency Medicine residents who had been trained for standardization for the NG intubation technique prior to the present study[12,13]. All intubations were confirmed for proper positioning of the NG tubes by abdominal auscultation or aspiration of gastric content.

Outcome measures

Within 10 minutes after intubation and the NG tube had been secured, data were collected using a predesigned questionnaire. Primary outcomes were patient's pain and discomfort as measured by a 100-mm visual analog scale (VAS). After being sprayed, patients were also asked for their satisfaction of the spray before NG intubation using a 5-point Likert Scale. Physicians who inserted the NG tubes were asked for the difficulty and satisfaction in NG intubation by 5-point Likert Scales. All patients and physicians were asked with the same question "whether they will choose the same spray that was used in that session for the next insertion".

The number of attempts, success rates and complications of NG intubation (epistaxis, choking and tracheal insertion) were recorded. Failure of NG intubation was defined by unsuccessful passage of the NG intubation for more than 3 attempts.

Statistical analysis

Patient's characteristics were analyzed by descriptive statistics (mean, median, standard deviation and range). Continuous data was calculated by Student T test. Ranking scale was evaluated by Mann-Whitney Test, and categorized data was compared by Pearson Chi Square or Fisher Exact Test. SPSS version 13 was used for statistical analysis.

The present study was approved by Siriraj Ethical Committees, Faculty of Medicine, Siriraj Hospital, Mahidol University. Funding was supported by the Routine to Research (R2R) Project, Faculty of Medicine, Siriraj Hospital. No pharmaceutical company was involved in any part of the recent study.

Results

Sixty patients were enrolled into the present study, 31 patients were randomized to the treatment group (10% lidocaine spray) and 29 to the placebo group (NSS spray). Demographic characteristics of patients in both groups are shown in Table 1. The lidocaine group had more females than the placebo group (64.5% vs. 27.6%, $p = 0.04$). Other parameters including gender, age, indications of NG intubation, patients' setting, previous experience of the patients with NG intubation, level of physicians who inserted the NG tube, size of NG tube, experience of patients and physicians with lidocaine spray were similar in both groups.

Patients' pain score was measured by VAS. Result in the lidocaine group was 23.6 ± 16.6 mm while the placebo group was 43.1 ± 31.4 mm ($p = 0.005$). Discomfort score was 30.0 ± 21.4 mm in the lidocaine group and 51.4 ± 30.0 mm in the placebo group ($p = 0.004$). More patients in the lidocaine group chose to have the same spray for their next intubation (93.5% vs. 63.5%, $p = 0.009$)

Physicians were more satisfied with lidocaine spray than placebo and 61.3% chose to have the same spray in their future insertion compared to 34.5% in the placebo group ($p = 0.038$). Difficulty of intubation, number of attempts and failure rate were not different among the 2 groups. No complication was found in both groups (Table 2).

Since patients in the lidocaine group were more predominantly female, gender might be a factor that affects the treatment outcomes. Multivariate analysis (linear regression) was performed, and confirmed that after being corrected for patient's gender, only the types of treatment (lidocaine or placebo spray) were significantly associated with degree of pain ($p = 0.007$) and discomfort ($p = 0.009$), but not the patient's gender ($p = 0.963$ and 0.832, respectively).

Discussion

NG intubation is a very common and important medical procedure but it inevitably causes pain and discomfort to the patients. Ineffective use of pain and discomfort reducing strategies may give the patients a bad experience during NG intubation and patients may refuse to have this procedure in the future. Although many studies demonstrate that almost every form of local anesthesia applied before NG intubation seems to be more effective than lubricant jelly alone, their use is rarely practiced. Reasons for the scanty usage include the unawareness of the physicians[10], the unavailability of the varieties of local anesthetic preparations used in the studies, i.e. 4% atomized lidocaine spray[1,2,5], 10% lidocaine spray[6], cetacaine spray[7], cocaine spray[5], 4% lidocaine nebulizer[3,6] or 2% lidocaine jelly[2,5,7] and finally, the varieties and inconveniences of each regimen, i.e. applying to

Table 2. Outcomes

Outcome	Type of spray		Mean difference	p
	Lidocaine (n = 31)	Placebo (n = 29)	(95% CI)	
Patients				
Pain, mean VAS ± SD (mm)	23.6 ± 16.6	43.1 ± 31.4	-19.6 (-6.7 to -32.4)	0.005
Discomfort, mean VAS ± SD (mm)	30.0 ± 24.4	51.4 ± 30.0	-21.4 (-7.3 to -35.5)	0.004
Satisfaction after being sprayed, median Likert scale (25^{th}-75^{th} percentile)	4 (3-5)	4 (3-5)		0.975
Choosing this spray for next intubation, n (%)				
Yes	29 (93.5)	9 (65.5)		0.009
No	2 (6.5)	10 (34.5)		
Physicians				
Satisfaction, median Likert scale (25^{th}-75^{th} percentile)	4 (3-5)	4 (3-4)		0.041
Difficulty of intubation, median Likert scale (25^{th}- 75^{th} percentile)	2 (1-3)	3 (2-3)		0.255
Choosing this spray for next intubation, n (%)				
Yes	19 (61.3)	10 (34.5)		0.038
No	12 (38.7)	19 (65.5)		
Procedure				
Duration of NG intubation, mean ± SD (sec)	65.3 ± 34.1	93.8 ± 96.8	-28.4 (-8.6 to 65.5)	0.689
Number of attempts, n (%)				
1	25 (80.6)	23 (79.3)		0.653
More than 1	6 (19.4)	6 (20.7)		
Failure of intubation, n (%)	0	2 (6.9)		0.229
Complication, n (%)	0	0		1.000

the nose alone[1,5] or using different preparations for nose and throat[7].

Siriraj Hospital, the usage of 2% lidocaine jelly lubrication alone is the standard application for NG intubation. However, this usage may be no more effective than using lubrication jelly because there is almost no contact time for the lidocaine to take effect. A 10% lidocaine spray preparation is commercial-available and has been extensively used in patients undergoing upper gastrointestinal endoscopy. Thus, the authors hypothesize that using 10% lidocaine spray prior to the application of 2% lidocaine jelly lubrication should be more effective than 2% lidocaine jelly alone in relieving patient's pain and discomfort from NG intubation.

The present study showed that 10% lidocaine spray together with 2% lidocaine jelly lubrication is more effective than lidocaine jelly alone in relieving patient's pain and discomfort from NG intubation. It also increases physician's satisfaction without adding any complications or difficulties to the procedure. Interestingly, the mean pain score (using VAS) in the presented control group was 43 mm, which is lower than 57-64 mm as reported in previous studies[2,3,7]. This may indicate that Thai patients have a higher pain threshold. Nevertheless, lidocaine spray can further reduce pain for 20 mm, compared to 22-28 mm in other studies[2,3,7].

In the presented questionnaire, which also evaluated the concern that 10% lidocaine spray might itself cause irritation to the nose or throat, had clearly shown that 10% lidocaine spray did not cause irritation or unsatisfying feeling compared to the placebo and there were no other side effects.

Although in the present study, blinding all patients and physicians from the type of spray used during intubation was strictly done, patients could often correctly guess the type of spray by the bitterness of lidocaine. However, patients had no idea that the bitter taste was actually lidocaine and physicians were

requested not to ask the patients how they felt or tasted about the spray.

Formerly, the authors postulated that only size of NG tube might influence the outcomes, thus the authors stratified patients by only the size of NG tube but not for patient's gender. However, after randomization, the distribution of gender was not equal between the studied groups. Anyway, to the authors' knowledge, there is no study showing the influence of gender on the pain and discomfort from NG intubation[1-7]. Although the authors used multivariate analysis adjusting for patient's gender to solve this problem and confirmed that only the types of treatment did affect patient's pain and discomfort, however, further study with stratification of patients by gender may be needed to clarify this issue.

Conclusion

The use of 10% lidocaine spray applied to the nose and throat prior to the application of 2% lidocaine jelly lubrication during NG intubation is more effective than applying 2% lidocaine jelly lubrication alone in alleviating a patient's pain and discomfort and it also increase physician's satisfaction without producing additional side effects. Application of this strategy should be a routine practice for physicians considering insertion of a NG tube on a patient.

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การเปรียบเทียบประสิทธิภาพระหว่างการใช้ยาพ่นลิโดเคนร่วมกับลิโดเคนเยลลี่กับการใช้ลิโดเคนเยลลี่อย่างเดียวสำหรับการใส่สายนาโสแกสตริก

สุพจน์ พงศ์ประสบชัย, ธัญจิรา จิรนันทกาญจน์, อัครินทร์ นิมมานนิตย์, เชิดชัย นพมณีจำรัสเลิศ

วัตถุประสงค์: *การใส่สายนาโสแกสตริกเป็นหัตถการที่ทำให้ผู้ป่วยเกิดความเจ็บปวดและไม่พึงพอใจได้มาก แม้จะมีข้อมูลว่าการใช้ยาชาเฉพาะที่ไม่ว่ารูปแบบใดๆก่อนการใส่สายนาโสแกสตริกดีกว่าการใช้เยลลี่หล่อลื่นเพียงอย่างเดียว แต่ในทางปฏิบัติมีการใช้จริงน้อยมากเนื่องจากความไม่สะดวกในการเตรียมหายาและวิธีการใช้ ผู้รายงานจึงทำการศึกษาเปรียบเทียบประสิทธิภาพระหว่างการใช้ยาพ่นลิโดเคนร่วมกับลิโดเคนเยลลี่กับการใช้ลิโดเคนเยลลี่อย่างเดียวในการใส่สายนาโสแกสตริก*

วัสดุและวิธีการ: *ผู้ป่วยที่มีข้อบ่งชี้ของการใส่สายนาโสแกสตริกจะถูกสุ่มเพื่อได้รับยาพ่นลิโดเคนความเข้มข้นร้อยละ 10 หรือยาหลอก (น้ำเกลือนอร์มัล) ที่จมูกและคอ หลังจากนั้นผู้ป่วยทั้งสองกลุ่มจะถูกใส่สายนาโสแกสตริกที่หล่อลื่นด้วยลิโดเคนเยลลี่ความเข้มข้นร้อยละ 2 แพทย์ผู้พ่นยา ผู้ใส่สายนาโสแกสตริก ผู้เก็บข้อมูลและผู้ป่วยจะไม่ทราบชนิดของยาพ่นที่ใช้หรือได้รับ*

ผลการศึกษา: *ผู้ป่วยทั้งหมด 60 ราย ได้รับยาพ่นลิโดเคน 31 ราย ได้รับยาหลอก 29 ราย กลุ่มที่ได้รับลิโดเคนเป็นเพศหญิงมากกว่ากลุ่มยาหลอก (ร้อยละ 65 เทียบกับร้อยละ 28, ค่าพี = 0.04) แต่อายุของผู้ป่วย ข้อบ่งชี้ของการใส่สายนาโสแกสตริก ขนาดของสายที่ใส่ และประสบการณ์ของแพทย์ผู้ใส่ไม่แตกต่างกัน ความรู้สึกไม่สุขสบายจากการถูกพ่นยาไม่แตกต่างกันระหว่างสองกลุ่ม แต่ในการใส่สายนาโสแกสตริก ผู้ป่วยกลุ่มลิโดเคนรู้สึกเจ็บปวดน้อยกว่า (visual analog scale 23.6 $\pm$ 16.6 มิลลิเมตร เทียบกับ 43.1 $\pm$ 31.4 มิลลิเมตร, ค่าพี = 0.005) รู้สึกไม่สุขสบายน้อยกว่า (30.0 $\pm$ 24.4 มิลลิเมตรเทียบกับ 51.4 $\pm$ 30.0 มิลลิเมตร, ค่าพี = 0.004) เมื่อเทียบกับกลุ่มที่ได้ยาหลอก ผู้ป่วยกลุ่มลิโดเคนร้อยละ 93 และกลุ่มยาหลอกร้อยละ 65 เลือกจะใช้ยาพ่นชนิดเดิมในการใส่ครั้งต่อไป (ค่าพี = 0.009) แพทย์ในกลุ่มลิโดเคนมีความพึงพอใจ (วัดโดยลิกเกิร์ตสเกล 5 แต้ม) มากกว่ากลุ่มยาหลอก (ค่าพี = 0.041) แพทย์กลุ่มลิโดเคนร้อยละ 61 และกลุ่มยาหลอกร้อยละ 34.5 เลือกจะใช้ยาพ่นชนิดเดิมในการใส่ครั้งต่อไป (ค่าพี = 0.038) ความยากง่ายในการใส่สายนาโสแกสตริก เวลาที่ใช้ในการใส่ จำนวนครั้งที่ใส่ และความสำเร็จในการใส่ไม่แตกต่างกันในทั้งสองกลุ่ม ผู้ป่วยทั้งสองกลุ่มไม่เกิดภาวะแทรกซ้อนใดๆ*

สรุป: *การใช้ยาพ่นลิโดเคนร่วมกับลิโดเคนเยลลี่มีประสิทธิภาพดีกว่าการใช้ลิโดเคนเยลลี่อย่างเดียวในการใส่สายนาโสแกสตริกในการลดความเจ็บปวดและไม่สุขสบายของผู้ป่วย เพิ่มความพึงพอใจของแพทย์ โดยไม่เกิดภาวะแทรกซ้อนใดๆเพิ่มขึ้น จึงควรนำวิธีการนี้มาใช้ในเวชปฏิบัติทั่วไป*