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ORIGINAL ARTICLE

Analgesic efficacy of 10% lidocaine spray during nasoenteral catheterization: Randomized triple-blind trial

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Abstract

Background: Pain is a common experience during nasoenteral catheterization. Although the procedure causes discomfort and distress to patients, procedural pain remains neglected and undertreated.

Objective: To evaluate the analgesic efficacy of the use of 10% lidocaine spray during nasoenteral catheterization.

Method: A randomized, triple-blind trial of 50 patients was performed. The patients were randomly assigned to two groups: an intervention group (IG), in which 10% lidocaine spray combined with 2% lidocaine gel was used, and a control group (CG), in which a saline solution spray combined with 2% lidocaine gel was used. Pain and discomfort were assessed during and after nasoenteral catheterization using numerical rating scale (NRS) and the visual analogue scale (VAS), respectively.

Results: Intervention group participants reported lower pain scores during (0.20 ± 0.71 vs. 5.00 ± 2.84, $p < .001$; $|d| = -0.677$) and after (0.00 ± 0.00 vs. 2.80 ± 2.83, $p < .001$; $|d| = -0.718$) nasoenteral catheterization compared to the CG.

Conclusion: Spraying 10% lidocaine spray before nasoenteral catheterization was most effective for relieving discomfort and pain, with lower pain and discomfort recorded in NRS and VAS. Topical administration of 10% lidocaine spray is therefore a suggested measure for procedural pain relief related to nasoenteral catheterization.

Significance: The use of 10% lidocaine spray was more effective in relieving procedural pain and discomfort during nasoenteral catheterization. Patients who received 10% lidocaine spray registered lower discomfort and pain scores than those from 2% lidocaine gel group; there were less complications among patients in the IG.

1 | INTRODUCTION

Procedural pain is a common phenomenon in the care of patients undergoing nociceptive procedures such as nasoenteral catheterization (NEC), which has great clinical relevance in the hospital setting (Halloran, Grecu, & Sinha, 2011). Despite being considered the fifth vital sign, pain, especially acute procedural pain, is still neglected and undertreated. Research has documented several harmful effects related to procedural pain, such as fear, anxiety, anger, aggressive behaviour and impairments in cardiopulmonary function, metabolic, inflammatory and immune responses (Czarnecki et al., 2011).

There are few reports of institutions that have adopted guidelines for procedural pain management, and few

trials evaluating pain management during gastrointestinal intubation have been reported in scientific journals (Kuo, Yen, Fetzer, & Lee, 2010; Lor et al., 2018). Unlike endoscopic procedures in which patients undergo sedation and analgesia, NEC is routinely performed in clinical practice using only 2% lidocaine gel at the distal tip of the catheter. Although the lidocaine gel acts as a local anaesthetic, its gel presentation has the additional effect of facilitating sliding of the catheter during insertion (Lor et al., 2018; Uri, Yosefov, Haim, Behrbalk, & Halpern, 2011).

Studies have compared the analgesic efficacy of 10% lidocaine spray during nasogastric tube (NGT) insertion with that of 2% lidocaine gel. The results demonstrated a reduction in discomfort and pain compared to a placebo group that received saline spray (Kuo et al., 2010; Pongprasobchai, Jiranantakan, Nimmannit, & Nopmaneejumruslers, 2007). However, the analgesic efficacy of the use of 10% lidocaine spray prior to NEC has not been investigated.

Considering the existing knowledge gap, this study aimed to evaluate the analgesic efficacy of 10% lidocaine sprayed in the nasal region during NEC. We believe that 2% lidocaine gel is insufficient for the relief of procedural pain related to NEC, and we hypothesize that 10% lidocaine spray is effective for this purpose.

2 | METHOD

2.1 | Study design and participants

A randomized, triple-blind trial was carried out in a tertiary hospital in Northeast Brazil during the months of November 2017 and August 2018.

We included patients who were adults or emancipated, had a medical prescription for NEC and were able to respond to questioning by the collection team during the evaluation (score 15 on the Glasgow Coma Scale). Participants who had a history of allergy to components of 10% lidocaine spray or 2% lidocaine gel were excluded from the study.

The sample size was calculated using the Miot (2011) formula (α of 1,96 and error value β of 0,80) and taking into account the study of Pongprasobchai et al. (2007) (a similar study whose GI had a DP of 16,6 and a mean of 23,6 as well as GC with a DP of 31,4 and a mean of 43,1), resulting in an ideal sample of 50 participants with 25 individuals allocated to each group. We use this sample strategy due to the lack of statistical data about the monthly prescriptions at the hospital where NEC data were collected.

Participants' baseline characteristics and pain descriptions were determined through collecting data about their gender, marital status, reasons for hospitalization, medical history, and pain and discomfort locations during and after NEC.

2.2 | Procedure and intervention

Insertion of the nasoenteral catheter (12-Fr) was performed in a standardized manner by the institution's professionals according to the institutional protocol and following clinical indications for enteral feeding and drug therapy. Eligible participants were randomized into two groups: an intervention group (IG) that received 10% lidocaine spray and a control group (CG) that received saline spray. In the IG, three sprays (0.3 ml) of a 10% lidocaine were applied to the nasal region chosen for catheterization 3 minutes prior to catheterization, and 2% lidocaine gel was applied to the distal tip of the nasoenteral catheter. In the CG, three sprays (0.3 ml) of saline solution were applied to the nasal region chosen for catheterization 3 minutes prior to catheterization, and 2% lidocaine gel was applied to the distal tip of the nasoenteral catheter.

Randomization of the trial subjects was accomplished using opaque, sealed envelopes containing the IG and CG specifications; the envelopes were sequentially numbered and were opened just prior to the beginning of the procedure. Masking of the intervention occurred using identical, opaque vials of saline solution and 10% lidocaine spray. In addition, the professional who evaluated the outcome was not the same individual who applied the solutions. Thus, the trial was considered triple blind because the participants, the principal investigator and the outcome evaluator were unaware of the participant allocations (Guyatt, 2008).

2.3 | Outcomes

The primary outcomes were pain and discomfort scores during and 30 min after the NEC. Pain was evaluated using the numerical rating scale (NRS), which is a single 11-point numeric scale that ranges from 0 to 10 in which 0 means "no pain" and 10 indicates "worst imaginable pain". Participants were requested to state their score verbally. We used an adapted version of the visual analogue scale (VAS) to measure discomfort. The VAS consists of a 100-mm horizontal line with endpoints representing extreme limits ranging from 0 (“no discomfort”) to 10 (“severe discomfort”) (Cullen, Taylor, Taylor, & Chu, 2004; Haefeli & Elfering, 2006). The participants marked their discomfort level on the line between the two endpoints.

Secondary outcomes were the ease of catheterization (measured with a 5-point Likert scale), catheterization time (minutes) and possible complications related to the procedure:

cough, nausea, vomiting, nasal bleeding, hypertensive peak, sneezing and dyspnoea.

2.4 | Statistical analysis

Descriptive data analysis was performed in which numerical variables were expressed as the mean ± standard deviation (*SD*), and qualitative variables were expressed as absolute and relative frequencies and odds ratios (ORs) with their respective 95% confidence intervals (95% CI). The normality of the data was verified using the Shapiro–Wilk test.

The analysis of the association between qualitative variables was performed using the Chi-square (χ^2) and Fisher's exact tests (Fisher, 1922). Since the distributions of the numerical variables were asymmetrical, we used the Mann–Whitney test to examine differences between the groups.

In addition, the magnitude of the effect was calculated using the Cliff Delta statistic (|d|). This measure can be understood as a useful complementary analysis to the corresponding hypothesis test since the *p*-values alone do not actually provide information about the magnitude of a difference between two groups of observations (Cliff, 2014). The Cliff Delta statistic ranges from −1 to 1 and is interpreted as follows: $|d| < 0.147$ - insignificant difference; $|d| < 0.33$ - small difference; $|d| < 0.474$ - moderate difference; other values indicate large differences (Romano, Kromrey, & Coraggio, 2006).

The level of significance adopted in all analyses was 5%. The data were analysed using R software version 3.4.2 (R Development Core Team, 2014).

2.5 | Ethical considerations

The investigation followed the recommendations set forth in the Declaration of Helsinki. The study was approved by the Ethics Committee of the Universidade Federal de Sergipe (Protocol 1,711,822) and was registered under Universal Trial Number (UTN) U1111–1211–637. The participants signed an informed consent form.

3 | RESULTS

Fifty participants, 25 in the IG and 25 in the CG, were included. A CONSORT flowchart representing the flow of patients is shown in Figure 1. The sample was considered homogeneous because there was no significant difference between the groups in the baseline characteristics of the participants, as shown in Table 1. Female patients were predominant in both groups, and the patients ranged in age from young to middle aged (IG vs. CG: 36.88 ± 17.6 years vs. 38.12 ± 20.06 years, $p = .889$). They were hospitalized due to infectious diseases, trauma or surgical procedures [GI vs.

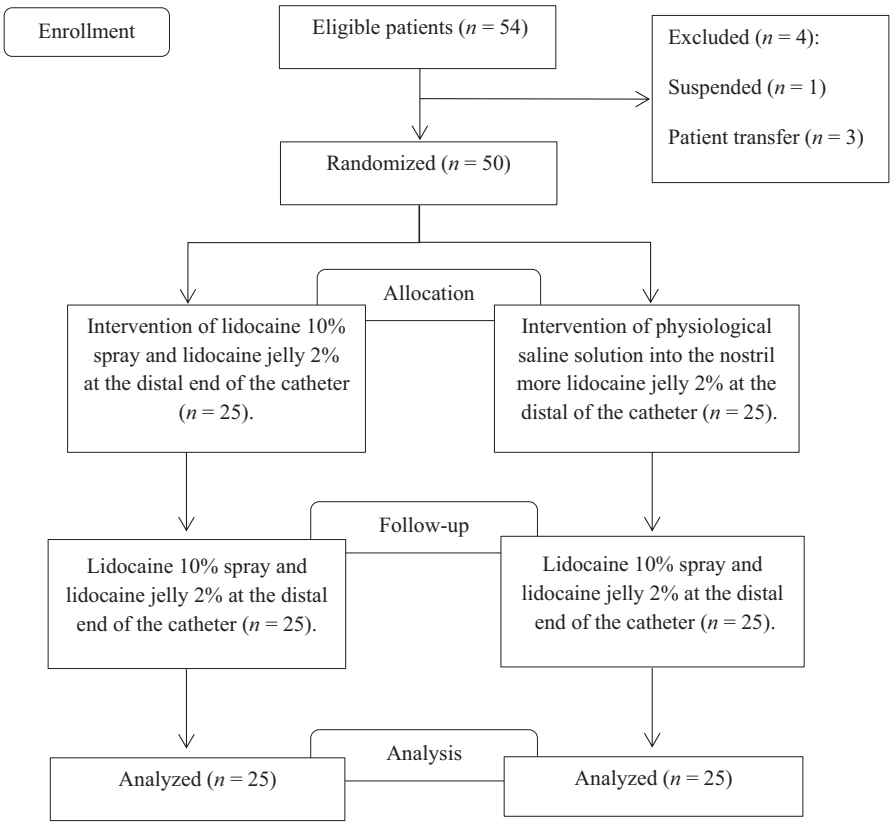

FIGURE 1 Flowchart of the study participants

TABLE 1 Baseline characteristics of the study participants

Variables	Group				OR (95% IC)	*p*-value
	IG		CG			
	n	%	*n*	%		
Gender						
Male	11	44	11	44	1.00 (0.33–3.06)	1.000[a]
Female	14	56	14	56		
Marital status						
No partner	14	56	19	76	0.41 (0.11–1.38)	.339[b]
Partner	11	44	6	24		
Reason for hospitalization						
Infectious disease	7	28	7	28	1.00 (0.29–3.44)	1.000[b]
Trauma	4	16	2	8	2.19 (0.36–13.22)	.667[b]
Surgical procedures	3	12	2	8	1.57 (0.24–10.30)	1.000[b]
Cancer	—	—	4	16	—	.109[b]
Dysphagia	2	8	1	4	2.09 (0.18–24.61)	1.000[b]
Other	9	36	9	36	1.00 (0.31–3.26)	1.000[a]
Medical history	11	44	13	52	0.73 (0.23–2.26)	.571[a]
Hypertension	7	28	6	24	1.23 (0.35–4.37)	1.000[b]
Diabetes	2	8	1	4	2.09 (0.18–24.61)	1.000[a]
Cancer	—	—	2	8	—	.489[b]
Other	2	8	4	16	0.46 (0.05–2.88)	.667[b]

[a]Chi-square test

[b]Fisher's exact test.

GC: 14 (56%) vs. 11 (44%)]. Almost half (48%) of the participants had some pathological history.

3.1 | Acute pain and discomfort

The pain, discomfort and location parameters are summarized in Table 2. The prevalence of pain was much higher in the CG at both moments of the assessment (IG vs. CG: 84% vs. 8% and 60% vs. 0%). Discomfort during and after the survey was also reported by the great majority of CG participants (96% and 84%, respectively). The nostril and nasopharynx were the most commonly reported sites of discomfort and pain. Participants who received sprays of 10% lidocaine reported lower pain and discomfort scores (Table 3). There was no difference between the groups in the ease or duration of the insertion procedure (Table 3).

3.2 | Main complications during and after NEC

Most CG patients had complications during and after the procedure, with no significant differences between groups. Regarding the type of complication recorded during the survey, nausea was most frequent in patients in both groups, and the most frequent complications after the procedure were coughing and nausea (Table 2).

3.3 | Effect size

The effect size was analysed using the Cliff Delta statistic. We observed a large difference between the IG and CG treatments in the reported intensity of discomfort during and after catheterization and the reported intensity of pain during and after the procedure (Table 3).

4 | DISCUSSION

A number of studies have shown an effect of lidocaine on the relief of pain related to nasogastric catheterization (Cullen et al., 2004; Kuo et al., 2010; Lor et al., 2018; Pongprasobchai et al., 2007; Uri et al., 2011; Wolfe, Fosnocht, & Linscott, 2000); however, to our knowledge, no study has tested its efficacy in NEC. To the best of our knowledge, our study is the first randomized, placebo-controlled, triple-blind clinical

TABLE 2 Characteristics of pain and discomfort related to NEC

	Group					
	IG		CG			
Variables	***n***	**%**	***n***	**%**	**OR (95% IC)**	***p*-value**
Presence of pain						
During catheterization	2	8	21	84	0.02 (0.00, 0.10)	.000[b]
After catheterization	—	—	15	60	—	.000[b]
Location of pain during catheterization						
Nostril	2	8	10	40	0.13 (0.03–0.68)	.018[b]
Nasopharynx	—	—	10	40	—	.001[b]
Pharynx	—	—	1	4	—	1.000[b]
Location of pain after catheterization						
Nostril	—	—	8	32	—	.004[b]
Nasopharynx	—	—	6	24	—	.022[b]
Pharynx	—	—	1	4	—	1.000[b]
Presence of discomfort						
During catheterization	11	44	24	96	0.03 (0.00–0.28)	.000[b]
After catheterization	9	36	21	84	0.11 (0.03–0.41)	.001[b]
Location of discomfort during catheterization						
Nostril	5	20	12	48	0.27 (0.08–0.95)	.073[a]
Nasopharynx	5	20	11	44	0.32 (0.09–1.12)	.129[a]
Pharynx	1	4	1	4	1.00 (0.06–16.93)	1.000[b]
Stomach	—	—	1	4	—	1.000[b]
Location of discomfort after catheterization						
Nostril	5	20	10	40	0.38 (0.11–1.33)	.217[a]
Nasopharynx	4	16	9	36	0.34 (0.09–1.30)	.196[b]
Pharynx	—	—	2	8	—	.489[b]

[a]Chi-square test.

[b]Fisher's exact test.

trial to compare the efficacy of 10% lidocaine spray and 2% lidocaine gel in pain relief during NEC. We suggest that spraying 10% lidocaine into the nostril prior to nasoenteral tube insertion is more effective than using 2% lidocaine gel alone in relieving acute procedural pain related to NEC (Table 4).

Lidocaine has proven to be an effective analgesic for pain relief during gastrointestinal intubation, regardless of its delivery method. A recent systematic review analysed different doses and delivery methods of lidocaine and showed the benefit of lidocaine in relieving procedural pain associated with NGT insertion, especially in the adult population, with a mean difference of −26.05 [95% CI: −28.21 to −23.89] (Lor et al., 2018). Another systematic review and meta-analysis that included 5 randomized clinical trials (RCTs) with 212 subjects investigated only the analgesic effect of nebulized lidocaine. The results showed an effect size of 0.423 (95% CI: 0.204 to 0.880), indicating that the use of nebulized lidocaine before NGT insertion can decrease pain. Nevertheless, the authors concluded that there was insufficient evidence to recommend the dosage, concentration or delivery method (Kuo et al., 2010). Both systematic reviews comprised RCTs that measured pain intensity through the VAS.

Our results are similar to those found in other RCTs that evaluated the analgesic effect of lidocaine during NGT insertion. Pongprasobchai et al. (2007) carried out a double-blind RCT with 60 patients from an emergency department (ED). The intervention consisted of spraying two puffs (1.4 ml) of 10% lidocaine into each nostril and six puffs into the throat 3 min before the nasogastric intubation with NGT (14F to 18F) lubricated with 3 ml 2% lidocaine jelly. The outcomes were measured within 10 min after NGT insertion. The results demonstrated a reduction in pain and discomfort assessed by the VAS. Another double-blind, placebo-controlled RCT that enrolled 50 patients with several clinical conditions from the ED of two hospitals showed that 4 ml of 10% lidocaine for nebulization combined with lubrication gel of the distal tip of the NGT decreased discomfort scores compared to the control group, as measured by the VAS (Cullen et al., 2004). The

TABLE 3 Analgesic efficacy analysis of 10% lidocaine spray

Variables	Group					
	IG		CG			
	Mean	SD[a]	Mean	SD[a]	*p*-value	|d| IG versus CG
Intensity of discomfort[b]						
During catheterization	1.84	2.54	5.48	2.60	.000	−0.677[d]
After catheterization	0.92	1.32	4.0	2.55	.000	−0.718[d]
Intensity of pain[c]						
During catheterization	0.2	0.71	5.0	2.84	.000	−0.822[d]
After catheterization	0.0	0.0	2.80	2.83	.000	−0.600[d]
Ease of catheterization	1.76	0.87	1.88	0.83	.538	−0.096[e]
Catheterization time (min)	4.08	1.53	4.08	1.68	.842	0.032[e]

[a]standard deviation.
[b]VAS.
[c]NRS.
[d]large difference.
[e]insignificant difference.

time frame of the discomfort measure was not standardized but was estimated to be between 1 and 10 min.

In accordance with these findings, a prospective, randomized, double-blind, placebo-controlled study that enrolled 62 ED patient demonstrated that patients who received 5 ml 2% lidocaine gel in the nasal region 5 min prior to NGT insertion reported lower pain VAS scores than patients who received only water-based lubricant in the nasal region (Uri et al., 2011). This result suggests that even lidocaine jelly can be effective for alleviating pain related to NGT if used properly.

NEC is commonly performed in hospital practice, especially for nutritional support, medication administration and drainage of body fluids. Patients undergoing this procedure often experience pain, discomfort and dissatisfaction as well

TABLE 4 Complications during and after NEC

Variables	Group					
	IG		CG			
	n	%	*n*	%	OR (95% IC)	*p*-value
Complications during catheterization	12	48	23	92	0.08 (0.02–0.42)	.001[b]
Cough	6	24	13	52	0.29 (0.09–0.98)	.080[a]
Nausea	9	36	21	84	0.11 (0.03–0.41)	.001[b]
Vomiting	—	—	3	12	—	.235[b]
Dyspnoea	1	4	4	16	0.22 (0.02–2.11)	1.000[b]
Nasal bleeding	—	—	1	4	—	1.000[b]
Hypertensive peak	—	—	1	4	—	1.000[b]
Complications after catheterization	6	24	21	84	0.06 (0.01–0.25)	.000[b]
Cough	4	16	13	52	0.18 (0.05–0.66)	.015[b]
Nausea	3	12	15	60	0.09 (0.02–0.39)	.000[b]
Vomiting	—	—	2	8	—	.489[b]
Nasal bleeding	—	—	1	4	—	1.000[b]
Dyspnoea	—	—	1	4	—	1.000[b]
Sneezing	—	—	1	4	—	1.000[b]

[a]Chi-square test.
[b]Fisher's exact test.

as a compromised self-image due to the presence of the device in their nasal or oral region (Ojo & Brooke, 2016). Therefore, although it uses smaller gauge tubes than nasogastric catheterization, NEC can cause patients suffering, discomfort and pain.

The mechanism by which lidocaine produces pain relief involves paralysis of peripheral sensory nerve endings, preventing pain from being transmitted by the nociceptors to the encephalon. We also know that lidocaine has an anti-inflammatory action, a characteristic that also promotes pain relief (Herroeder et al., 2007; Kaba et al., 2007). However, we note that the way in which its use has been advocated in the standardization of the NEC procedure seems to be innocuous since there is no preventive administration and it is used only as a lubricant for the catheter.

The guarantee of painless procedures is a fundamental right of patients (Kuo et al., 2010). Pain management for NEC is important to promote convenience, patient welfare and especially the relief of pain while avoiding detrimental effects such as tachycardia, increased blood pressure and hypoxaemia (Lima et al., 2017; Ribeiro et al., 2012).

In addition to the efficacy of 10% lidocaine spray in the relief of pain and discomfort of patients subjected to NEC, the percentage of complications related to the procedure was lower in the IG. The catheterization time and ease of insertion by the professional were evaluated to investigate whether the use of 10% lidocaine spray affected these variables. We did not observe significant differences, leading us to assume that these variables are more strongly influenced by professional experience and practice.

The strengths of this study are related to its robust methodology and the measurement of effect size. We conducted the triple-blind study using a random allocation of participants to reduce bias. In addition, since the *p*-values alone did not express the magnitude of the difference between the groups studied, we evaluated the difference in intensity between treatments using the Cliff Delta statistic. We found a considerable difference between treatment with 10% lidocaine spray and treatment with 2% lidocaine gel alone. This finding corroborates the hypothesis that 10% lidocaine spray is more effective than the standard care of only lubricating the distal end of the catheter with 2% lidocaine gel.

The lack of protocols and clinical guidelines for procedural pain management was a difficulty in data collection in this study. For this reason, some professionals questioned the feasibility of using 10% lidocaine spray in clinical practice. In Brazil, the standard care in most institutions is only the lubrication of the catheter with 2% lidocaine gel. Due to legal limitations, nurses can only prescribe drugs, such as 10% lidocaine spray, when institutional protocols allow them to do so.

The results of our triple-blind controlled trial demonstrate that the use of three sprays of 10% lidocaine (0.3 ml) prior to NEC was more effective for acute pain relief than lubrication of the distal end of the catheter with 2% lidocaine gel alone. Therefore, we suggest that the intervention used in this study be added to existing analgesia protocols, sparing patients from the undesirable consequences that pain related to NEC may cause.

CONFLICT OF INTERESTS

None declared.

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