Lidocaine/Phenylephrine Nasal Spray versus Nebulization Prior to Nasoendoscopy: A Randomized Controlled Trial

Liang Chye Goh, MRCS(ENT)¹,², Balachandran Arvin, MS(ORL-HNS)², Abu Bakar Zulkiflee, MS(ORL-HNS)¹, and Narayanan Prepageran, MS(ORL-HNS)¹

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objective. To objectively compare the nasal decongestion potency of lidocaine/phenylephrine when delivered with a nasal nebulizer and a nasal spray before a rigid nasoendoscopic examination.

Study Design. Open-label randomized controlled trial.

Setting. Multicenter study.

Methods. This prospective clinical trial involved 106 participants with untreated chronic rhinitis. Fifty-three participants had 400 µL of lidocaine/phenylephrine administered into the right nostril with a nasal nebulizer, while the remaining 53 participants had 400 µL administered with a nasal spray. The control was the left nostril. Nasal resistance at 150-Pa fixed pressure was evaluated with an active anterior rhinomanometry at 5, 10, 15, and 30 minutes postintervention. Pain score was assessed subjectively by applying pressure to the inferior turbinate 30 minutes after intervention.

Results. There was an overall reduction in nasal resistance of the right nostril when lidocaine/phenylephrine was administered with the nasal nebulizer in comparison with the nasal spray. However, a statistically significant difference in nasal resistance was seen only at 5 minutes (P = .047), 15 minutes (P = .016), and 30 minutes (P = .036). The examining endoscopist further supported the degree of nasal decongestion via subjective assessment of the nasal cavity (P = .001). Pain scores obtained after the intervention showed a significant decrease in pain threshold when the nasal nebulizer was used instead of the nasal spray (P = .040).

Conclusions. This study suggests that the delivery of lidocaine/phenylephrine to the nasal cavity by the nasal nebulizer provides better decongestive and analgesic potency as compared with the delivery by nasal sprays.

Keywords

nebulizer, rhinomanometry, decongestion, endoscope, randomized controlled trial, multicenter

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Lidocaine/phenylephrine is a widely available nasal spray used by otorhinolaryngologists for decongestion and local anesthesia of the nasal cavity before a nasoendoscopic examination. It is often used in an outpatient setting and is useful before minor nasal procedures. It is unique in its properties because it provides local anesthetic and decongestive effects on the nasal mucosa, which lead to increased visualization of the nasal cavity and better comfort before a planned procedure in the nasal cavity.

Pharmacologically, lidocaine/phenylephrine is composed of lidocaine 5% (50 mg/mL) and phenylephrine 0.5% (5 mg/mL) and is often marketed in a 50-mL bottle attached to a disposable positive displacement atomizer, which avoids contamination by preventing backflow into the nozzle tip. Each spray comprises about 100 µL of medication and delivers approximately 5 mg of lidocaine and 0.5 mg of phenylephrine.¹ Its decongestive agent (phenylephrine) acts by influencing the sympathetic vasculature tone through alpha-adrenoceptors. Since its properties are sympathomimetic and oppose vasodilation, this leads to a decrease in nasal airway resistance, which facilitates nasal breathing.² ³ The local

¹Department of Otorhinolaryngology, University of Malaya Medical Center, Kuala Lumpur, Malaysia
²Department of Otorhinolaryngology, Hospital Tengku Ampuan Rahimah, Klang, Malaysia

Corresponding Author:
Liang Chye Goh, MRCS(ENT), Department of Otorhinolaryngology, University of Malaya Medical Center, Jalan Universiti, 50603 Kuala Lumpur; Wilayah Persekutuan, Kuala Lumpur, Malaysia.
Email: juliusglc@hotmail.com
anesthetic component (lidocaine) is a local amide anesthetic that blocks fast voltage-gated sodium channels in the cell membrane of postsynaptic neurons, hence preventing depolarization that collectively leads to hypoesthesia before a nasoendoscopy. Despite its advantages, there are disadvantages in the usage of such a device. The need for a new nozzle head after each usage is necessary to avoid the risk of contamination and infection.

A powered nasal nebulizer is a nasal delivery device in clinical practice for topical medication into the nasal cavity. Several studies demonstrated promising results in the efficacy of nebulized medication and its distribution into the nasal cavity and paranasal sinuses of healthy individuals and cadaver models. Its reported advantages over the traditional nasal spray are better distribution of medication throughout the nasal cavity and decreased long-term cost given that a new disposable applicator is not required for each patient. Very little information is available about the efficacy of lidocaine and phenylephrine delivered with the nasal nebulizer before an endoscopic examination of the nasal cavity. This study aims to compare the potency of lidocaine and phenylephrine when given in the nasal cavity with powered nasal nebulization versus conventional nasal sprays.

Methods

Study Population

Participants aged 18 to 40 years of age who met the inclusion criteria were enrolled in the study after providing written informed consent. Participants who visited the otorhinolaryngology clinic for clinical symptoms suggestive of moderate to severe persistent rhinitis, as described by the 2016 ARIA guidelines (Allergic Rhinitis and Its Impact on Asthma), were recruited into the study. Not all participants enrolled in the study had skin prick tests done to confirm the presence of atopy. Participants were excluded from the study if they had a history of bronchial asthma, ischemic heart disease, cystic fibrosis, diabetes, antihistaminic/anti-leukotriene usage, and intranasal or systemic steroid usage. Furthermore, participants who had nasal polyps, nasal septal perforation, granulomatous lesions, nasal masses, or previous nasal surgery, as determined during the clinical examination, were excluded from the study.

Study Design

This study was a prospective multicenter open-labeled randomized controlled trial conducted in the Department of Otorhinolaryngology of the University of Malaya Medical Center and Hospital Tengku Ampuan Rahimah, Malaysia. The researcher (L.C.G.) was aware of the delivery device used for each participant but was not in control of the random sequence of group assignment. Randomization of groups was performed electronically by graphpad.com, where the total number was separated into 2 groups (nasal spray and nasal nebulizer), with each group containing 60 samples. The study was registered with the US National Library of Medicine ClinicalTrials.gov database (NCT03380715; National Institutes of Health). The Malaysian Research ethical committee approved of the clinical trial before its commencement. All participants were enrolled from the outpatient clinic of the Department of Otorhinolaryngology in Hospital Tengku Ampuan Rahimah, Malaysia, from May 2016 to July 2017 and from the otorhinolaryngology outpatient clinic of the University of Malaya Medical Center from July 2017 to January 2018. The protocol is summarized according to the CONSORT flow diagram in Figure 1.

Intervention

Participants in the nasal spray group were given 4 sprays of lidocaine (400 µL to 20 mg) and phenylephrine (2 mg) into the right nostril, while the left nostril was left as a control. Participants who were in the nasal nebulizer group had 400 µL of lidocaine/phenylephrine (diluted in 4.5 mL of normal isotonic saline) delivered into the right nostril for 1 to 2 minutes. The nasal nebulizer device was directed into the lateral nasal wall, and the participant was asked to flex the head until nebulization was complete. The powdered nebulizer released particles 18 µm in size to nebulize the right nostril, while the left nostril was kept as a control.

Outcome and Statistical Analysis

The participant was first assessed with rigid nasoendoscopy (Storz 0° rigid nasoendoscope) for intranasal pathology before commencement of the study. If an intranasal pathology was present, the participant was labeled a dropout and excluded from the study. Subjective pain scores were assessed with the visual analog scale (VAS) before intervention and 30 minutes after intervention. Pain was evaluated by applying pressure to the anterior end of the inferior turbinates by using a Jobson-Horne probe under rigid nasoendoscopic examination for approximately 30 seconds. Objective assessment of nasal resistance (Pa/cm³) was assessed with an active

Figure 1. CONSORT diagram of the randomized controlled trial. CONSORT, Consolidated Standards of Reporting Trials.
anterior rhinomanometer (Atmos Rhino 31) preintervention and at 5-, 10-, 15-, and 30-minute postintervention intervals. A subjective endoscopist assessment of nasal congestion before and 30 minutes after intervention was also assessed with the VAS score, whereby a score of 10 was the worst congestion and 1 the least congestion, as described by the endoscopist. Taste sensation at the end of assessment was categorized into 2 groups: bitter taste or no aftertaste. Active anterior rhinomanometry was performed according to the guidelines of the Standardisation Committee on Objective Assessment of the Nasal Airway.12 The primary outcome of this study was nasal resistance at different intervals after the intervention, and the secondary outcome was the pain VAS scores, subjective endoscopist assessment of nasal decongestion, and aftertaste.

Pallanch et al13 performed a clinical trial evaluating nasal resistance among 80 subjects pre- and postdecongestion with phenylephrine nasal spray and reported a decrease in mean nasal resistance from 1.1 to 0.7 at 0.1-L/s nasal flow after 5 minutes of decongestion. Using the 2-proportion sample size calculation with a type I error of 5%, we calculated a target sample size of 53 participants in each arm (106 in total) to achieve an 80% statistical power. Analysis of data was conducted with SPSS 23 (IBM, Armonk, New York). Pain VAS score and nasal resistance were analyzed by first determining the confidence interval and subsequently analyzing the significant difference with the independent \( t \) test. The chi-square test was used to test for statistical significance when variables were categorical. A \( P \) value < .05 was considered statistically significant. The participants were then treated according to standard hospital protocol for chronic rhinitis and were followed up after 1 month.

**Results**

**Participant Overview**

One hundred and six participants who met the inclusion criteria were enrolled in the study. The participants were then randomized into 2 groups: nasal spray (n = 53) and nasal nebulizer (n = 53). The participants were between 18 and 40 years old (mean age, 27.1 years) and included 50 men and 56 women. No significant side effects were reported by participants in either group. Both groups (nebulizer and spray) had a significant decrease in nasal resistance when compared with control (ie, left nostrils).

### Table 1. Nasal Resistance Difference of the Right Nostril: Pre- minus Postintervention.a

<table>
<thead>
<tr>
<th>Min</th>
<th>Nasal Spray (n = 53)</th>
<th>Nasal Nebulizer (n = 53)</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>(-0.06 (\ -0.10 \text{ to } -0.02))</td>
<td>(-0.2 (\ -0.32 \text{ to } -0.07))</td>
<td>.047</td>
</tr>
<tr>
<td>10</td>
<td>(-0.09 (\ -0.14 \text{ to } -0.05))</td>
<td>(-0.21 (\ -0.34 \text{ to } -0.07))</td>
<td>.123</td>
</tr>
<tr>
<td>15</td>
<td>(-0.09 (\ -0.12 \text{ to } -0.06))</td>
<td>(-0.27 (\ -0.40 \text{ to } -0.13))</td>
<td>.016</td>
</tr>
<tr>
<td>30</td>
<td>(-0.12 (\ -0.17 \text{ to } -0.07))</td>
<td>(-0.28 (\ -0.42 \text{ to } -0.14))</td>
<td>.036</td>
</tr>
</tbody>
</table>

*a* A negative value denotes a decrease in nasal resistance from baseline and hence an improvement in nasal airflow.

**Change in Nasal Resistance**

The assessment of change in nasal resistance was compared between the right nostril of the 2 groups (nasal nebulizer and nasal spray). There was a statistically significant decrease in nasal resistance of the nasal nebulizer group when compared with the nasal spray group at 5, 15, and 30 minutes postintervention (Table 1, Figure 2). All phases of the control group (left nostril) had no statistically significant change in nasal resistance postintervention (Table 2, Figure 3).

**Change in Pain VAS Score, Nasal Decongestion, and Aftertaste**

The postintervention pain VAS scores improved in both groups. The nasal nebulizer group experienced a significantly lower pain VAS score as compared with the nasal spray group (\( P = .040; \) Table 3). Subjective endoscopist assessment of nasal decongestion indicated a significant difference at the end of 30 minutes, as suggested by the active anterior rhinomanometry findings in favor of the nasal nebulizer group over the nasal spray group (\( P = .001; \) Table 4). Fifty-three percent of participants experienced a bitter aftertaste 30 minutes postintervention. There was no statistically significant difference in the aftertaste (\( P = .697 \)) felt by the participants when the nasal nebulizer was used to deliver lidocaine and phenylephrine to the nasal cavity as compared with the nasal spray (Table 5).
Intranasal delivery devices have been used for a myriad of reasons, including topical and systemic indications, for many years. Topical applications to the nasal cavity have been used for the delivery of steroids, decongestants, hemostatic solutions, and so forth. Among the most frequent use of intranasal delivery devices is the use of nasal sprays in the delivery of local decongestants into the nasal cavity.14 Nasal spray bottles are often used to deliver decongestants into the nasal cavity. Although its definite advantage is the ease of use, its disadvantages include a random dose distribution and contamination of liquid within the nasal spray by organisms when nasal secretions are sucked into the bottle after pressure is released from the nozzle.7,15 Frequent changing of nasal spray nozzles avoids contamination of the bottle contents but could implicate further costs at the expense of hygiene. Dose and distribution of medication are highly dependent on the direction and how vigorous the application is pressed.16 Furthermore, Frank et al showed, using computational fluid dynamics, that nasal sprays have a tendency for posterior particle distribution, as compared with the nasal nebulizer, when used in the less congested side of the nasal cavity.17

The nasal nebulizer has the advantage of higher surface area distribution as compared with conventional nasal sprays,18,19 especially when particle size exceeds 10 μm.17 Furthermore, the nasal nebulizer provides predictable particle size and dose of medication retention into the nasal cavity. The higher surface area is a result of slower deposition of small particles, which increases particle penetration into the middle superior turbinates and paranasal sinuses.20 The clear disadvantage of the nebulizer is the risk of lung aspiration when the particle size is <10 μm.19 Moreover, there is an increased duration needed to deliver medication into the nasal cavity as compared with a nasal spray.

The results obtained from this clinical trial show that lidocaine/phenylephrine, when used with the nasal spray and nasal nebulizer, had significant decongestion at all postintervention intervals when compared with the left nostril (control). The results suggest that when nasal nebulizers (with a particle size of 18 μm) or nasal sprays are used, crossover to the contralateral nostril through the postnasal space is unlikely. Clinically significant nasal decongestion of the right nostril in the nasal nebulizer group was obtained at 5, 15, and 30 minutes after intervention. While lidocaine/phenylephrine led to nasal decongestion through sympathomimetic action in

### Table 2. Mean Nasal Resistance Difference of the Left Nostril: Pre- minus Postintervention.a

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<td>0.07 (–0.12 to –0.02)</td>
<td>.112</td>
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<td>10</td>
<td>0.03 (–0.07 to 0.01)</td>
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### Table 3. Mean Visual Analog Scale Pain Score Difference between Participants Using the Nasal Spray and the Nasal Nebulizer.a

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*aP < .05, independent t test.

**Discussion**

Intranasal delivery devices have been used for a myriad of reasons, including topical and systemic indications, for many years. Topical applications to the nasal cavity have been used for the delivery of steroids, decongestants, hemostatic solutions, and so forth. Among the most frequent use of intranasal delivery devices is the use of nasal sprays in the delivery of local decongestants into the nasal cavity.14

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Figure 3. Difference in nasal resistance of the left nostril (control group).

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the initial 5 minutes, nasal decongestion may be retarded by mucosal edema due to the volume of water being given in conjunction with the nasal nebulizer or nasal spray. After 10 minutes of intervention, mucosal edema reduces as the water clears from the nasal cavity and sympathomimetic action becomes predominant once more. This finding is likely due to the higher distribution of medication throughout the nasal cavity.

Although this study identified the potential of nasal nebulizers in the decongestion and local analgesia of the nasal cavity, there are a few limitations to it. The nasal cycle involves alternating physiologic periods of nasal cavity congestion; hence, when decongestants are delivered to the less congestive side of the nasal cavity, less decongestion may be observed versus the delivery of decongestants to the more congested nostril. Furthermore, as this is an assessment of lidocaine/phenylephrine in chronic rhinitis, further studies need to be done to validate its potency for pathologic conditions such as nasal polyposis, chronic rhinosinusitis, and severe deviated nasal septum. As this study is an open-label clinical trial, subjective interpretation of decongestion by the endoscopist and participant selection may also serve as a source of bias.

However, we see the potential for the use of the powered nasal nebulizer for preoperative decongestion before a minor intranasal surgical procedure, such as simple uncinectomy, polypectomies, and turbinoplasties, but further studies need to be performed to confirm this. Other avenues for future studies may include a comparison of the degree of decongestion and pain relief when medication is delivered with a powered nasal nebulizer against the same amount on cottonoid pledges against the inferior turbinates for a period of time.

**Conclusion**

There are a few implications of this clinical trial. While other studies showed poor penetration of medication into the sinuses in sinusitis,20,21 this study demonstrates that powered nasal nebulizers provide better objective and subjective decongestion and better subjective pain relief from delivery by a nasal spray.

**Acknowledgments**

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**Author Contributions**

Liang Chye Goh, conception and design, data collection, data analysis and interpretation, drafting of article, and approved the final version of the manuscript; Balachandran Arvin, conception and design, data collection, data analysis and interpretation, critically revising article, and final approval of the version to be published; Abu Bakar Zulkiflee, data collection, data analysis, critical revision of the article, and final approval of the version to be published; Narayanan Prepageran, data analysis and interpretation, critical revision of the article, and final approval of the version to be published.

**Disclosures**

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**References**


