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Efficacy of Lubrication of the Laryngeal Mask Airway with Benzydamine Hydrochloride Spray versus Chamomile Extract Spray for Prevention of Postoperative Sore Throat: a Randomized Controlled Trial

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Abstract

Background: Despite the i-gel® being considered less traumatic to the airway, the incidence of postoperative sore throat (POST) remains high. Various drugs, including benzydamine hydrochloride (BH) spray, have been studied for their ability to reduce POST, but no studies have examined the efficacy of chamomile extract spray. This study aims to compare the efficacy of BH and chamomile extract sprays in reducing the incidence of POST after general anesthesia (GA) with the i-gel®.

Methods: In this randomized controlled trial, a total of 228 patients undergoing surgery under GA with the i-gel® were assigned into one of three groups. Prior to induction of anesthesia, the i-gel® was sprayed with 4 puffs of BH, chamomile extract, or normal saline in the BH, chamomile, and control groups, respectively. The primary objective of the study was to compare the incidence of POST among the three groups at 1, 4, and 24 hours after surgery.

Results: The study found that the incidence of sore throat was significantly different at the 4th hour postoperatively, being lowest (28.4%) in the chamomile group and highest (50.0%) in the control group (P=0.023). Moreover, the severity of sore throat was significantly different between the chamomile and control groups at the 4th postoperative hour (P=0.015), while chamomile demonstrated greater efficacy than BH in reducing POST (RRR 43.0%, 15.0%, respectively).

Conclusion: Spraying 4 puffs of chamomile extract on the i-gel® before insertion effectively reduces incidence and severity of POST at 4-hour post-surgery.

Keywords: sore throat, laryngeal mask, chamomile, benzydamine hydrochloride

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Introduction

Despite the laryngeal mask airway (LMA) being considered to cause less airway trauma than endotracheal tubes, the incidence of post-operative sore throat (POST) with LMA use remains high, ranging from 5.8-34%.[1-3] POST typically results from compression of the pharynx by the cuff of the LMA. However, even though i-gel® (Intersurgical Ltd., Wokingham, UK) does not present overinflation concerns, POST can still occur, with an incidence as high as 28.4%.[2] Various drugs have been studied for their ability to decrease POST, including lidocaine gel, propofol, nonsteroidal anti-inflammatory drugs (NSAIDs), steroids, propolis and benzydamine hydrochloride (BH).[3-9] A 0.3% benzydamine hydrochloride spray has been shown to be effective in reducing the incidence of POST when used with the LMA ProSeal™ Airway and LMA Unique™.[9,10] Chamomile is a common anti-inflammatory plant extract used to soothe sore throats associated with common colds.[11]

Lubricating the endotracheal tube cuff with chamomile extract spray before intubation was found ineffective in preventing POST in several previous studies.[12,13] There is currently no evidence demonstrating the efficacy of chamomile extract spray in reducing POST after the use of a LMA. So, we decided to conduct a study to compare the efficacy of both BH and chamomile in reducing POST following the use of LMA. Our decision to evaluate POST symptoms at 1, 4, and 24 hours after the operation is based on the previous studies indicating that these time points are particularly crucial, as POST tends to be most prevalent during these intervals.[10,12,14] The primary objective of this study was to compare the incidence of POST following general anesthesia with the i-gel® at 1, 4, and 24 hours postoperatively among patients using 0.3% benzydamine hydrochloride spray, chamomile extract spray and normal saline sprayed on the i-gel®. The secondary objectives were to compare the severity of POST among the three groups at 1, 4, and 24 hours following the operation, as well as evaluating the efficacy of these medications.

Methods

A randomized, controlled trial was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines and was registered with the Thai Clinical Trials Registry (TCTR20230324005). The study was conducted between August and December 2022 at a tertiary care hospital's department of anesthesiology and operating room. It received approval from the Institutional Ethics Committee (COA/2 No.004/2565), and all patients provided written consent before participating. The trial was double-blinded, and the investigators-maintained compliance with ethical standards throughout the study.

The sample size calculation for the study was performed using STATA statistical software based on a previous study, which reported that the incidence of patients without POST at the 4th postoperative hour was 82.5% in the BH group, while the control group had 60% of patients without sore throat (P=0.03).[10] Another study revealed that 52.5% of patients receiving chamomile had no POST, while 50.6% of those receiving normal saline did not develop POST (P=0.159).[13] When comparing these findings with the triad criteria, the group receiving normal saline without sore throat symptoms in the second study was 60.0%, consistent with the first study.[10] The calculated results indicated

that patients in the chamomile group without sore throat symptoms accounted for 62.3%. The analysis utilized binary data and a superiority-binary outcome, with a *P*-value of 0.05, a 0.05 type-I error, and 80% power of the test. Participants were randomized into three groups: a control group, a BH group, and a chamomile group, initially totaling 205 individuals. To accommodate potential participant withdrawals, the sample size was increased by 10%, resulting in a total of 228 individuals, consistently distributed across three groups with 76 participants each. In order to control the risk of bias in this randomized controlled trial and address potential selection bias, the random allocation of 228 patients into the BH, chamomile, and control groups was designed to ensure an impartial distribution of both known and unknown confounding factors.

The study comprised patients between the ages of 18 and 75 years old with American Society of Anesthesiologists (ASA) physical status I to III who were scheduled to undergo surgery using the i-gel® LMA under general anesthesia. Patients with any of the following were excluded: contraindication for using LMA, allergies to NSAIDs or chamomile, severe liver or kidney diseases, pregnancy or within 6 weeks postpartum, body mass index (BMI) more than 30 kg/m^2, operation involving the head, neck or cervical spine, upper respiratory tract infection within 7 days prior to the operation, retained nasogastric tube, operation under lateral or prone position, and operation time exceeding 3 hours. Patients were excluded from the study if the LMA was replaced with an endotracheal tube, if the LMA was inserted more than twice, or if they were unable to provide information until 24 hours after surgery.

In the BH group, the i-gel® was sprayed with 4 puffs (2 mg) of 0.3% benzydamine hydrochloride spray (Difflam™ Forte Anti-Inflammatory Throat Spray, Inova Pharmaceuticals, Italy), whereas the suggested dose is 2 to 4 puffs (1-2 mg) every 1.5 to 3 hours.[15] In the chamomile group, the i-gel® was sprayed with 4 puffs (150 mg) of chamomile extract spray (Kamillosan®M, MEDA Pharma GmbH & Co. KG, Germany). In the control group, 4 puffs of normal saline were sprayed onto the i-gel®. Only the investigator who sprayed the study drug onto the LMA was aware of the study group, and both the patients and the anesthetists were blinded to the study drug.

Propofol (1.5-2.5 mg/kg), fentanyl (1-2 µg/kg) or morphine (0.1-0.2 mg/kg), and succinylcholine (1-1.5 mg/kg) were used to induce general anesthesia. After achieving a sufficient level of anesthetic, the i-gel® was placed using the standard method, with the i-gel® size determined by the patient's weight.[16] The patient's anesthesia was maintained using a 60% mixture of nitrous oxide, oxygen, and sevoflurane. During the surgical stimulation, the end tidal carbon dioxide concentration was kept between 25 and 40 mmHg, and the sevoflurane concentration was adjusted to ensure a sufficient depth of anesthesia. During surgery, opioids were supplied to patients to provide effective pain relief. After the patient regained consciousness following surgery, the LMA was removed. The incidence and severity of sore throat were assessed by trained anesthetists who were unaware of the study drug at 1, 4 and 24 hours after LMA removal. We measured sore throat severity using the same 4-point scale used in a previous study[12] as reviewed by four anesthesiologists: 0 = none, 1 = less severe than with a common cold, 2 = as severe as with a common cold, and 3 = more severe than with a common cold. We also recorded sex, age, height, body weight, ASA

physical status, underlying diseases, smoking history, anesthetic time, LMA size and number of insertion attempts, the quantity of opioid used during the operation, respiratory complications (laryngospasm, bronchospasm, desaturation, and cough upon LMA removal), and study drug side effects (numbness, burning, and dry mouth).

Statistical analysis was conducted with Statistical Package for the Social Sciences (version 26.0; IBM Corporation, Armonk, NY, USA). Means and standard deviations were calculated for age, weight, height, LMA insertion attempts, operation time, and amount of morphine utilized intraoperatively. To compare proportions, the Chi-square and Fisher's exact tests were used. We determined the severity of sore throat using the Kruskal-Wallis-test followed by Mann-Whitney U test without alpha level adjustment for multiple comparisons between groups. Significant differences were defined as those having *P*-value of <0.05. The relative risk reduction (RRR) was used to compare the efficacy of reducing the incidence of POST between the control group and the BH or chamomile groups. The absolute risk reduction (ARR) was calculated to determine the actual reduction in POST risk between these groups. Finally, the number needed to treat (NNT) was used to assess the number of patients who needed to be treated with 0.3% BH or chamomile sprays to prevent one occurrence of POST.

Results

We enrolled 228 patients in our study, 76 patients in each group. Three patients were

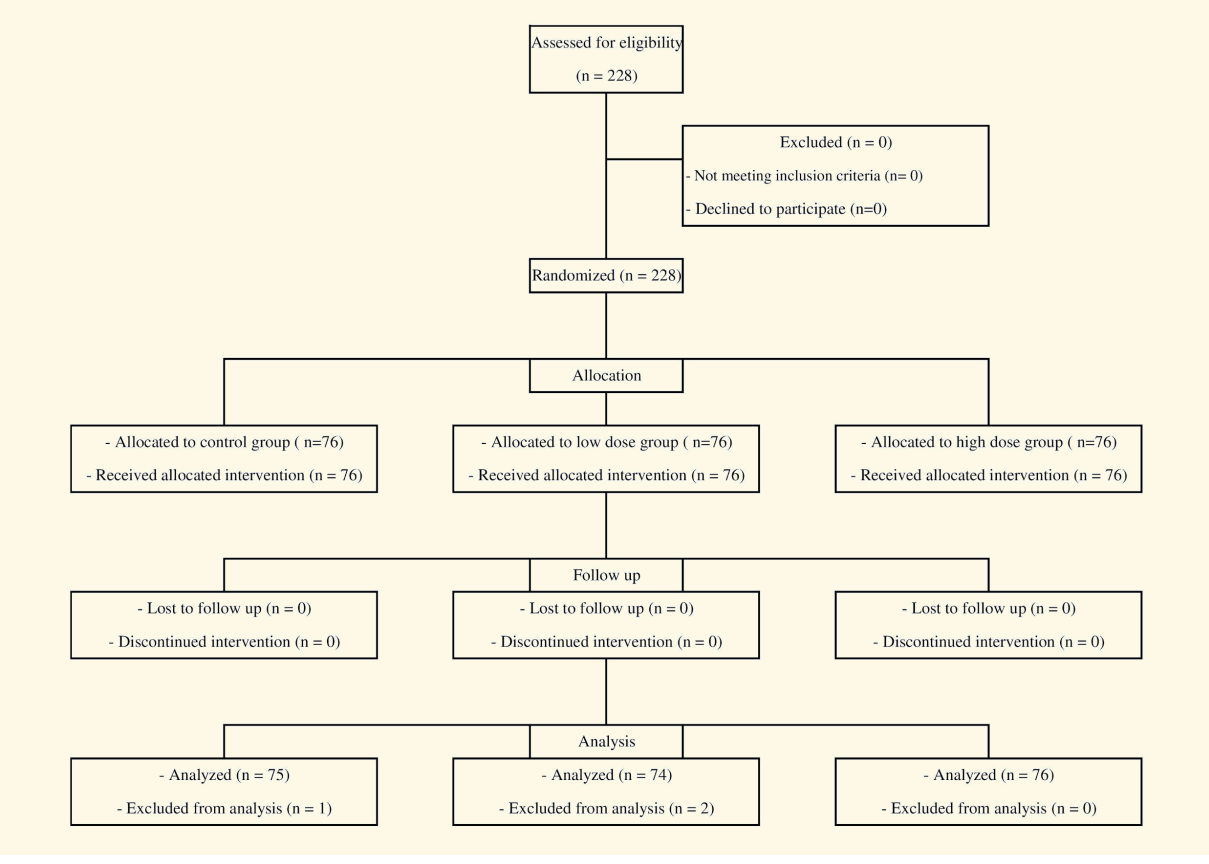


Figure 1 Consolidated standards of reporting trial diagram

excluded from the analysis because their surgeries lasted longer than three hours. (Figure 1)

The mean age of the patients was 48.6± 15.8 years in the BH group, 49.1±14.8 years in the chamomile group and 48.7±15.4 years in the control group. There were no differences in demographic data including sex, age, weight, height, ASA physical status, smoking habit, LMA sizes and insertion attempts, operation duration, and intraoperative opioid use between the three groups. (Table 1)

At the 1st postoperative hour, the incidence of sore throat was found to be highest in the group treated with 0.3% BH spray (38.7%) and lowest in the control group (26.3%), although the difference was not statistically significant. However, at the 4th postoperative hour, a significant difference (*P*=0.023) was observed in the incidence of sore throat patients, with the lowest proportion found in the group treated with chamomile extract spray (28.4%) and the highest in the control group (50.0%). By the 24th postoperative hour, the incidence of sore throat patients was lowest in the chamomile group (21.6%) and highest in the BH group (22.7%), although there was no significant difference observed between the groups. (Table 2)

We utilized the Kruskal-Wallis's test to analyze the severity of POST among the three groups. Our results indicated no significant differences in sore throat severity between the groups at the 1st or 24th postoperative hour.

Table 1 Demographic data

Parameters	BH group (n=75)	Chamomile group (n=74)	Control group (n=76)	*P*-value
Gender (male/female) (n)	46/29	43/31	48/28	0.814
Age (yr, mean±SD)	48.6±15.8	49.1±14.8	48.7±15.4	0.910
Weight (kg, mean±SD)	60.5±11.2	58.9±10.3	60.6±10.8	0.582
Height (cm, mean±SD)	163.5±8.7	160.4±8.1	162.0±7.8	0.070
ASA physical status (n) I II III	 29 40 6	 28 43 3	 26 45 5	0.839
Smoking (smoker/nonsmoker/ former smoker)	18/42/15	24/44/6	21/45/10	0.297
Laryngeal mask airway size (No.3/4/5) (n)	24/42/9	24/46/4	23/45/8	0.693
LMA insertion (attempt, mean±SD)	1.1±0.2	1.0±0.1	1.1±0.3	0.176
Operative time (min, mean±SD)	54.4±28.2	58.2±34.1	52.3±30.6	0.500
Perioperative opioid Morphine (mg, mean±SD) Fentanyl (n, %) Pethidine (n, %)	 6.9±2.7 2 (2.7) 1 (1.3)	 6.2±2.8 1 (1.4) 4 (5.4)	 6.5±2.6 1 (1.3) 3 (3.9)	 0.332 0.848 0.408

ASA = American Society of Anesthesiologists

Table 2 Incidence of sore throat

	At 1st postoperative hour			At 4th postoperative hour			At 24th postoperative hour		
	S/N	%	*P*-value	S/N	%	*P*-value	S/N	%	*P*-value
BH group (n=75)	29/46	38.7	0.266	32/43	42.7	0.023*	17/58	22.7	0.988
Chamomile group (n=74)	25/49	33.8		21/53	28.4		16/58	21.6	
Control group (n=76)	20/56	26.3		38/38	50.0		17/59	22.4	

S/N: sore throat/ non-sore throat, % = percent of sore throat, *Significant at *P*-value <0.05

However, a significant difference was observed between the groups at the 4th postoperative hour (*P*=0.047). (Table 3)

Due to the violation of normality and equal variance assumptions in our data, we employed the Mann-Whitney U test to evaluate the severity of sore throat at the 4th postoperative hour. Our findings revealed a significant difference between the chamomile and control groups (*P*=0.015). There were no statistically significant differences between the BH and chamomile groups or between the BH and control groups. (Table 4) Table 5 presents the RRR and ARR of the BH and chamomile groups compared with the control group at 4 hours postoperatively. Our results revealed that the RRR for the BH

Table 3 Severity of sore throat

	BH group (n=75)	Chamomile group (n=74)	Control group (n=76)	*P*-value
At 1st postoperative hour	0 (0, 1)	0 (0, 1)	0 (0, 1)	0.359
At 4th postoperative hour	0 (0, 1)	0 (0, 1)	0.5 (0, 1)	0.047*
At 24th postoperative hour	0 (0, 0)	0 (0, 0)	0 (0, 0)	0.998

Data are expressed as the median (interquartile range). *Significant at *P*-value <0.05

Table 4 Severity of sore throat at 4th postoperative hour

	BH group (n=75)	Chamomile group (n=74)	Control group (n=76)	*P*-value
At 4th postoperative hour, mean±SD median (IQR)	0.45±0.55 0 (0,1)	0.35±0.61 0 (0,1)	-	0.126
	0.45±0.55 0 (0,1)	-	0.57±0.64 0.5 (0,1)	0.317
	-	0.35±0.61 0 (0,1)	0.57±0.64 0.5 (0,1)	0.015*

Data are expressed as the median (interquartile range). *Significant at *P*-value <0.05

Table 5 Relative risk reduction, absolute risk reduction and number needed to treat at 4th post-operative hour

	Sore throat in treatment group n (%)	Sore throat in control group (n=76) n (%)	RR (95% CI)	RRR (%)	ARR (%)	NNT
BH (n=75)	32 (42.7)	38 (50.0)	0.85 (0.60-1.21)	15.0	7.3	13.64
Chamomile (n=74)	21 (28.4)	38 (50.0)	0.57 (0.37-0.87)	43.0	21.6	4.62

RR= risk ratio, CI = confidence interval, RRR = relative risk reduction, ARR = absolute risk reduction, NNT = number needed to treat

Table 6 Complications

Parameters	BH group n (%)	Chamomile group n (%)	Control group n (%)	*P*-value
Numbness	2 (2.7)	0	2 (2.6)	0.550
Burn	4 (5.3)	2 (2.7)	3 (3.9)	0.844
Dry mouth	11 (14.7)	12 (16.2)	15 (19.7)	0.695

group was 15.0%, while the chamomile group showed a higher RRR of 43.0%. Additionally, the NNT for the BH and chamomile groups were 13.64 and 4.62, respectively.

During the study, we did not observe any serious complications or adverse drug reactions in any of the three groups. Additionally, we found no significant differences in the incidence of complications such as numbness, burning, and dry mouth between the groups. (Table 6)

Discussion

Postoperative sore throat is a frequently encountered issue that can impact patient satisfaction and restrict daily activities following surgery. Numerous studies have been conducted to identify effective methods for reducing POST following the insertion of LMA. Kiran and colleagues have found that applying betamethasone 0.05% gel to the cuff of a ProSeal LMA may help decrease the incidence of POST after elective surgeries.[7] Chairatthanawanit and coworkers discovered that spraying the LMA ProSeal™ airway cuff with 0.3% BH spray increased the number of patients who did not experience POST at the 4th postoperative hour and reduced its severity at the 1st and 4th hours.[10] Meanwhile, Earsakul and colleagues have reported that applying 0.3% BH spray and water-soluble gel to the LMA Unique™ cuff resulted in a decreased incidence of POST during rest and swallowing at the 1st and 2nd hour after surgery without causing any additional side effects related to BH spray use.[9]

Our study revealed a significant difference in the incidence of POST among the three groups at 4 hours after the procedure. However, there

was no significant difference noted at 1 and 24 hours, which aligns with the findings of a previous study.[10] In our study, the majority of patients were administered morphine intraoperatively, which has a duration of approximately 4 hours.[17] Therefore, even at 1-hour post-surgery, the effects of the intraoperative opioid were still present, which explains the low occurrence of sore throat at this stage. In a related study, Earsakul and colleagues reported that the occurrence of POST during periods of rest and swallowing was significantly lower in the group that received 0.3% BH spray than in the control group at 1 and 2 hours following the surgical procedure.[9] The dissimilarity in the type of LMA used and the method of evaluating sore throat could be potential reasons for the observed difference in outcomes.

At 4 hours postoperatively, the incidence of sore throat was lowest in the chamomile group, while it was highest in the control group, with a significant difference. A previous study was shown no advantage of tracheal cuff lubrication with chamomile puff spray before intubation.[12] No previous studies have explored the use of chamomile extract spray with any type of LMA insertion. Our study found that using chamomile extract spray on the LMA prior to insertion could potentially reduce the incidence of POST. This is likely due to the different mechanisms of POST generated by endotracheal tubes and LMA. Sore throat after tracheal intubation is usually attributed to trauma of the tracheal mucosa.[18] However, LMA-induced POST is believed to result from pharynx compression. Therefore, we suggest that chamomile extract spray could potentially alleviate this mechanism, similar to how it is used for the common cold.

The results of the study showed that the severity of sore throat was significantly different between the chamomile and control groups 4 hours after the operation. Due to the limited understanding of the pharmacokinetics and pharmacodynamics of chamomile extract spray, the recommended dosage according to the drug leaflet is three times a day.[19] Each dose is expected to provide relief for a duration of 6-8 hours,[19] while 0.3% BH spray requires dosages every 1.5-3 hours.[15] There was an improvement in the severity of sore throat 24 hours after surgery, which could be attributed to various factors, such as the natural healing process of inflammation or the utilization of oropharyngeal suction during the emergence phase.

The efficacy of 0.3% BH spray and chamomile extract spray in reducing POST was assessed. The BH group demonstrated a 15.0% reduction in the risk of developing POST compared to the control group, necessitating treatment for approximately 13.6 patients to prevent an additional case of POST in comparison. Conversely, the chamomile group had shown a 43.0% reduction in the risk of developing POST, requiring treatment for only 4.6 patients to prevent an additional case of POST. These results highlighted the superior efficacy of chamomile extract spray over the 0.3% BH spray in reducing the risk of developing POST. These findings implied that both 0.3% BH and chamomile extract spray could be viable options in mitigating the incidence of POST, with chamomile extract spray showing greater efficacy. Complications including numbness,

dry mouth, and burning, were documented in relation to the study drugs[9,14], but there was no significant difference in the occurrence of complications between the drugs studied. This implies that both 0.3% BH and chamomile extract spray may be considered safe for use with the LMA.

The study had a few limitations. One of the main limitations was the lack of recommended dosages for BH and chamomile extract sprays on the LMA. As a result, we had to rely on the dosages recommended for treating sore throat due to the common cold and previous studies to determine the appropriate dosages for this study.[9,10] Second, the study did not record the use of analgesic drugs during the postoperative period, which could potentially affect the severity of sore throat experienced by patients. Furthermore, the study only evaluated the incidence of sore throat at specific time intervals and did not assess the duration of sore throat. Last, succinylcholine was used in every patient, even though there were some studies suggesting that the use of muscle relaxants for LMA insertion could increase the severity of sore throat.[20] To enhance the efficacy of chamomile extract spray, additional data on the duration, onset, and peak effect of the drug are necessary, and they could be used to improve the study design. Future studies should also explore the drug's efficacy without muscle relaxants during LMA insertion, determine the optimal dosage and duration of chamomile extract spray and record postoperative opioid use for more precise clinical recommendations. Further studies with larger sample sizes and more comprehensive evaluations of sore throat are recommended to provide more robust conclusions.

Conclusion

Our findings indicate that applying chamomile extract spray to the i-gel® before insertion can be regarded as a safe and effective intervention for reducing incidence and severity of POST at the 4-hour mark post-surgery. Moreover, chamomile exhibits superior efficacy compared to BH in this context. Therefore, we recommend this approach for the management of POST in clinical practice.

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