LUNG CENTER OF THE PHILIPPINES
Scientific Proceedings

ORIGINAL ARTICLE

EFFICACY AND SAFETY OF BUTAMIRATE CITRATE AS PRE-MEDICATION TO ALLEVIATE POST-BRONCHOSCOPY COUGH: A DOUBLE-BLIND RANDOMIZED PLACEBO-CONTROLLED TRIAL

Paul Justin S. Dizon, MD, DPBA, Ma. Stephanie G. Balaoing, MD, DPBA, Lizbeth G. Jacaban, MD, DPBA
Thoracic Surgery and Anesthesia Department, Lung Center of the Philippines

ABSTRACT

Background. Post-bronchoscopy cough is a common complication after fiberoptic bronchoscopy procedure despite the use of several medications and technique to suppress it.

Objective. This study aimed to evaluate the efficacy and safety of butamirate citrate, a centrally acting antitussive, in alleviating post-bronchoscopy cough.

Methodology. Patients scheduled for fiberoptic bronchoscopy under total intravenous anesthesia with controlled ventilation using laryngeal mask airway were randomized to receive butamirate citrate 2 hours prior to the procedure or a similar looking placebo tablet. Severity of cough was evaluated by the outcome assessor using a modified cough severity score at the 1st, 6th and 12th hour post-bronchoscopy and the patient's discomfort using visual analogue score (VAS) which was determined by the participants. The heart rate, blood pressure, and oxygen saturation were also assessed including the adverse events of medications.

Results. A total of eighty-four (84) patients scheduled for fiberoptic bronchoscopy under total intravenous anesthesia with controlled ventilation using laryngeal mask airway were randomly allocated in a double-blind, parallel-group trial. Forty-two (42) patients received butamirate citrate 2 hours prior to the procedure and the other thirty-four (34) patients received a similar looking placebo tablet. Eight (8) participants were withdrawn from the study. Based on the intention-to-treat analysis, median cough severity score was significantly lower in the butamirate group at the 1st (p= 0.0291) and 12th hour (p=0.0366) post- bronchoscopy. Higher proportion of patients in butamirate citrate group had no cough and it was statistically significant at the 12th hour (p=0.032). Patient's discomfort based on VAS, median change in systolic blood pressure and mean change heart rate were not significantly different from the two groups. Oxygen saturations of all patients were normal. One patient had nausea, and another presented with urticaria in the butamirate group but not significantly different with placebo.

Conclusion. Butamirate citrate is efficacious and safe as a premedication in alleviating post-bronchoscopy cough in patient undergoing FOB under total intravenous anesthesia with controlled ventilation using laryngeal mask airway based on the modified cough severity score, but it does not affect patient's discomfort, heart rate and blood pressure.

Keywords: butamirate citrate, post-bronchoscopy cough, fiberoptic bronchoscopy

Corresponding Author:
Paul Justin S. Dizon, MD
Lung Center of the Philippines
Contact Number: 0933 417 1068
Email: pauljustindizon@gmail.com

Year Completed: 2024
Date Received: 10 April 2025
Date Accepted: 01 July 2025

INTRODUCTION

Flexible fiberoptic bronchoscopy (FOB) is both a diagnostic and therapeutic procedure that is commonly performed to identify and treat abnormalities in the airways such as malignancy, infection, or inflammation.[1] Although considered to be safe, it is not without complications and discomfort.[2,3] Post-bronchoscopy cough was studied in two papers with an incidence of 10.8% and 55.7%.[3,4] In the study by Dang et al. post-procedural cough may present within 4 hours and up to 48 hours post procedure.[3]

There were limited studies that focus on post-procedural cough. One study investigated premedication with dextromethorphan, a centrally acting antitussive, and showed to suppress cough after FOB. This is not readily available in our institution and is a derivative of codeine.[5]

Of note, there is no standard treatment that is currently used for post-bronchoscopy cough.

A commonly used cough suppressant that is safe and readily available is butamirate citrate. It directly acts on the cough receptors in the brainstem and not related to opioids. It is readily absorbed with a peak plasma concentration within 1 hour and with a long duration of action of up to 12 hours. The adverse reactions that are considered to be rare are drowsiness, nausea, diarrhea, and urticaria.[6–9]

The purpose of this randomized, double-blind, placebo-controlled study is to determine if butamirate citrate premedication efficacious and safe in relieving post-bronchoscopy cough in patients undergoing FOB in an established conventional anesthesia technique in our institution. If proven effective and safe, butamirate citrate may be part of the medications to be given preoperatively. This study followed the Consort 2025 guidelines for reporting randomized clinical trials.

METHODOLOGY

The study was a randomized, double-blind, parallel-group trial. Study site was Lung Center of the Philippines, a Department of Health designated national specialty center for the diagnosis and management of lung and chest diseases. Bronchoscopic procedures, being facilitated by pulmonologists and thoracic surgeons, are done under general anesthesia by the thoracic anesthesiologists. Study duration was 5 months (May 2024 to September 2024).

Adult patients > 19 years-old who were scheduled for fiberoptic bronchoscopy under total intravenous anesthesia with controlled ventilation using laryngeal mask airway were recruited and properly screened by the Principal Investigator. Patients who have 1)known allergy to butamirate citrate; 2) pregnant and breastfeeding mother; 3) known case of liver cirrhosis and renal failure 4) concurrent expectorant medications 6) more invasive procedures such as cryoablation therapy, intralesional cisplatin injection, and rigid bronchoscopy 7) high aspiration risk 8) small mouth opening and patients with oropharyngeal abnormalities which could make the insertion of the LMA difficult were excluded from the study. Withdrawal criteria were as follows: 1) Patient refused to continue participation, 2) Cancelled FOB procedure, 2) sudden hemodynamic instability or other inciting event during the procedure (eg. myocardial infarction, stroke, aspiration, bleeding), 4) conversion to rigid bronchoscopy 5) conversion from laryngeal mask airway to endotracheal tube.

PASS 2021 software was used to calculate the minimum sample size required. Specifying a minimum clinically significant difference of 3 in cough severity and alpha set at 0.05, a minimum of 66 patients—33 per group—are needed to achieve 90% statistical power. Sample size was increased to 84—42 per group—to account for 20% potential dropout.

Those who fulfilled all the inclusion criteria and none of the exclusion criteria and has voluntarily signed in the informed consent were considered eligible. After assignment of a specific patient code, an independent researcher not involved in any other study procedure generated an allocation schedule which contains a list of patient numbers randomly assigned in a 1:1 ratio into two treatment groups: butamirate citrate and placebo. The independent researcher prepared opaque envelopes containing the either butamirate citrate tablet or placebo which were labelled with numbers. The treatment allocation was concealed from all patients, personnel who will perform the procedure, and outcome assessors.

Patients assigned to treatment group received Butamirate citrate sustained-release tablet 50mg tablet (Sinecod Forte, Novartis Saglik, Gida Ve Tarim Urunleri San. Tic. A.S. distributed by GSK Philippines). Patients assigned to placebo group received a similar looking tablet produced by Herbanext Laboratories, Inc, Negros Occidental in a cGMP manufacturing facility. The medications were given 2 hours prior to the procedure with minimal sips of water.

Once the patient arrived at the bronchoscopy unit, standard monitors were attached. Patients were induced with placement of laryngeal mask airway (LMA) ProtectorTM. Patients were maintained with total intravenous anesthesia using propofol. After the procedure, the LMA was removed, and nasal cannula or face mask was used for oxygen support. Patients were then transferred to the PACU.

Primary outcomes were (1) the severity of cough, assessed by the outcome assessors who were the anesthesia fellow-in-charge and/or the nurse-in-charge using the modified cough severity score which was derived from the simplified cough score (SCS) developed by the Respiratory Branch of Chinese Medical Association as a tool for evaluating the severity of cough (Figure 1), and (2) patient's discomfort which was self-evaluated by the patient using the VAS score (Figure 2).[10] Secondary outcomes were the heart rate, systolic blood pressure, oxygen saturation, and adverse

events of medications. The patients were assessed at the 1st, 6th and 12th hour post-procedure.

Data were encoded in MS Excel by the researcher. Stata MP version 17 software was used for data processing and analysis. Continuous variables were presented as mean (standard deviation/SD) and median (interquartile range/IQR) depending on the data distribution. Mann Whitney U test was used to compare the modified cough severity score and change in systolic blood pressure between the two groups, while independent t test was used to compare the change in heart rate. Change in systolic blood pressure and heart rate was also categorized (no change/increased/decreased), and comparison between the two groups was done using Fisher's Exact test. Fisher's Exact test was also used to compare patient's discomfort based of VAS score, proportion of patients presenting with no cough and desaturation, and adverse effects. Multiple linear regression analysis was also performed for the primary outcome (i.e., cough severity) to control for the effect of the significant confounder (i.e., bronchoscopy procedure). All randomized patients were included in the intention-to-treat analysis, and mode imputation was performed for modified cough severity score and patient's discomfort based on VAS score. P values ≤0.05 were considered statistically significant.

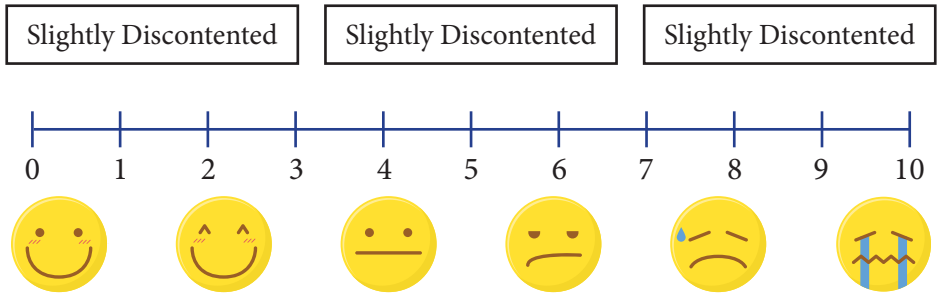

Figure 1. *Modified Cough Severity Score used to assess cough severity*

Modified Cough Severity Score	
0	No cough
1	Occasional cough for short periods
2	Frequent cough which interferes with recovery
3	Distressing coughs, which seriously affects recovery

Figure 2. *Visual Analog Scale used to assess patient's discomfort*

ETHICAL CONSIDERATIONS

This study was approved for implementation by the Lung Center of the Philippines Institutional Ethics Review Board (LCP IERB Code: LCP-AF-002-2024). Informed consent was taken to affirm voluntary participation before enrolment of participants. Patients were also reminded that they may refuse to participate or continue participation without any negative consequence to the care they will receive from LCP.

RESULTS

There are 107 patients scheduled for bronchoscopy under under total intravenous anesthesia with controlled ventilation using laryngeal mask airway from May 2024 to September 2024. Twenty-three were excluded due to not meeting inclusion criteria (n = 8), declined to participate (n = 3), BMI > 35 (n=4), renal failure (n=2), Cisplatin injection (n=4) and for rigid bronchoscopy (n=2).

A total of 84 patients were enrolled in the study—44 in the butamirate citrate group and 40 in the placebo group. Eight patients were withdrawn—2 from butamirate and 6 from placebo group. Two from placebo group refused to continue participation and the remaining six patients were converted to endotracheal tube.

The median age of all patients was 58.5 [IQR: 44.5-65; Range: 22-70 years]. Fifty two percent were 19 to 59 years old and 57% were males. Most patients presented with chronic cough both in butamirate citrate group (89%) and placebo group (92%). The examination time is usually longer for both groups which is equal to more than 60 minutes.

No significant difference was observed between the two groups except bronchoscopy procedure as shown in Table 1. More patients in the placebo group underwent cryobiopsy (33%) in the placebo group as compared to the butamirate group (11%). It is also noted that no patients assigned to

placebo underwent bronchial washing and 4 (9%) in the butamirate group.

INTENTION–TO–TREAT (ITT) ANALYSIS

The median cough severity score was significantly lower in the butamirate group at the 1st (p=0.0291) and 12th hour (p=0.0366) post bronchoscopy. Higher proportion of patients in butamirate citrate group had no cough and it is statistically significant at the 12th hour (p=0.032).

When controlled for the confounding effect of bronchoscopy procedure, the results were not statistically significant at 1st (p=0.17, p=0.380), 6th (p=0.10, p=0.569), and 12th (p=0.09, p=0.510) hour.

Patient discomfort based on VAS did not significantly differ between the two groups at 1st, 6th and 12th hour Median change in SBP was not significantly different between the two groups at 1st, 6th and 12th hour even when categorized. Mean change in HR was not significantly different between the two groups at 1st, 6th and 12th hour even when categorized. All patients in both groups had normal O2 saturation at 1st, 6th and 12th hour, thus, no comparison was done.

For the adverse effects, per-protocol analysis was used. A total of 76 participants were included, excluding 8 patients withdrawn from the study due to conversion to endotracheal tube and refusal to continue participation. There was no significant difference between the two groups in any of the adverse effects as shown in Table 3.

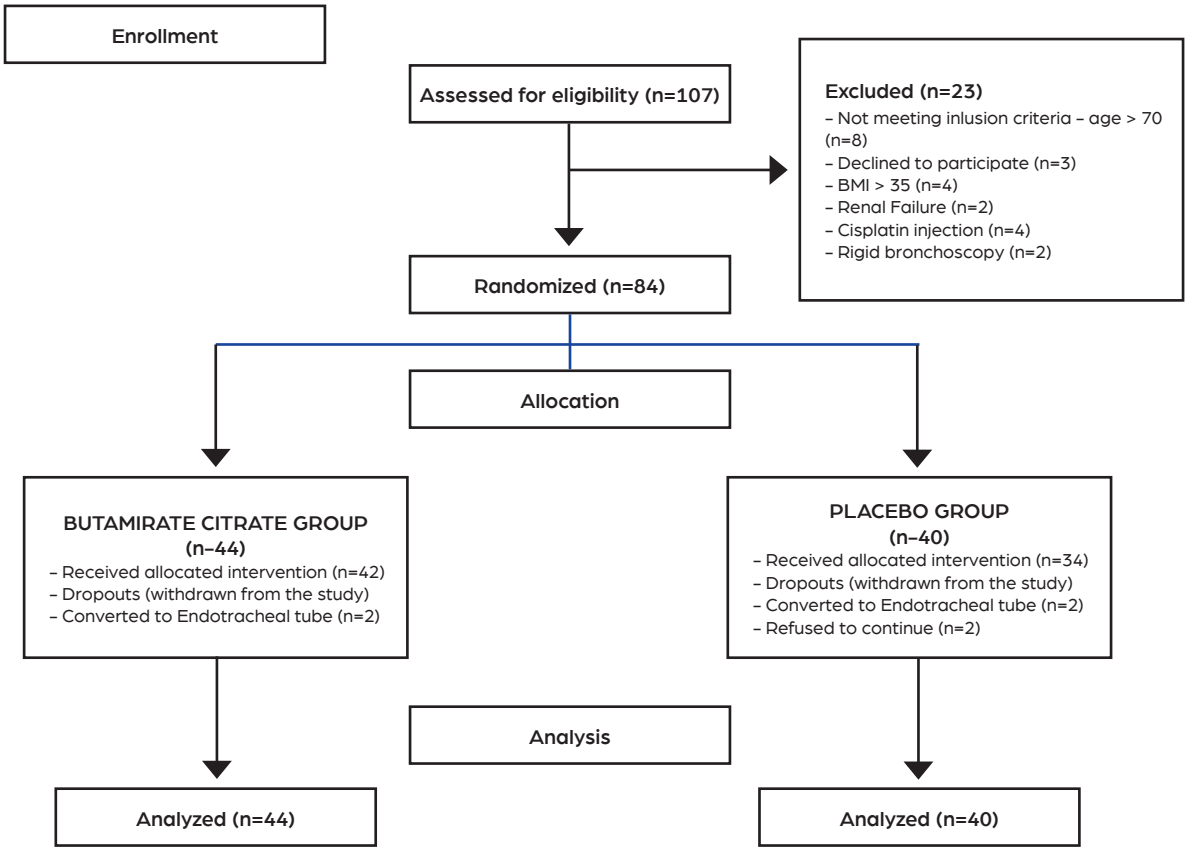

Figure 3. *CONSORT Study flow diagram*

Table 1. *Baseline characteristics of patients: butamirate citrate vs. placebo (n=84)*

	BUTAMIRATE CITRATE (n=44) n (%) Median [IQR]	PLACEBO (n=40) n (%) Median [IQR]	P VALUE
Age (in years), median	60 [IQR: 51, 67]	56 [IQR: 42.5, 64.5]	0.1176[a]
19–59 years old	21 (48)	23 (58)	0.370[b]
60–70 years old	23 (52)	17 (42)	
Sex			
Female	17 (39)	19 (47)	0.412[b]
Male	27 (61)	21 (53)	
Chronic cough			
No	5 (11)	3 (8)	0.715[c]
Yes	39 (89)	37 (92)	
Examination time			
Short procedure	10 (23)	3 (8)	0.054[b]
Long procedure	34 (77)	37 (92)	
Bronchoscopy procedure			
Endobronchial forceps biopsy	10 (23)	3 (8)	0.009*[c]
Bronchial washing	4 (9)	0	
EBUS with TBNA	18 (41)	22 (55)	
Cryobiopsy	5 (11)	13 (33)	
BAL	4 (9)	1 (2)	
Radial EBUS	3 (7)	1 (2)	

[a]Mann Whitney U test; [b]Chi square test; [c]Fisher's Exact test
**Statistically significant based on P value =<0.05*

Table 2. *Efficacy measures: butamirate citrate vs. placebo (n=84)*

	BUTAMIRATE CITRATE (n=44) n (%) Mean ± SD Median [IQR]	PLACEBO (n=40) n (%) Mean ± SD Median [IQR]	P VALUE
Severity of cough based on modified cough severity score, median			
1st hour	1 [IQR 1, 2]	2 [IQR: 1, 2]	0.0291*a
6th hour	1 [IQR: 0, 2]	1 [IQR: 1, 2]	0.1549a
12th hour	1 [IQR: 0, 1]	1 [IQR: 1, 1]	0.0366*a
No cough, %yes			
1st hour	10 (23)	3 (8)	0.054b
6th hour	12 (27)	5 (13)	0.092b
12th hour	17 (39)	7 (18)	0.032*b
Patient discomfort based on VAS at 1st hour	13 (30)	10 (25)	0.641b
Patient discomfort based on VAS at 6th hour	5 (11)	7 (18)	0.422b
Patient discomfort based on VAS at 12th hour	5 (11)	5 (12)	1.000c

	BUTAMIRATE CITRATE (n=44) n (%) Mean ± SD Median [IQR]	PLACEBO (n=40) n (%) Mean ± SD Median [IQR]	P VALUE
Change in SBP, median			
1st hour	3 [IQR: –5, 13]	0 [IQR: –5, 15]	0.8566[a]
No change	1 (2)	0	0.271[c]
Decreased	16 (36)	20 (50)	
Increased	27 (61)	20 (50)	
6th hour	–1.5 [IQR: –9.5, 5]	–2.5 [IQR: –10, 1.5]	0.3826[a]
No change	2 (4)	2 (5)	0.657[c]
Decreased	24 (55)	26 (65)	
Increased	18 (41)	12 (30)	
12th hour	–5 [IQR: –10, 2.5]	–7.5 [IQR: –13, –1.5]	0.1566[a]
No change	1 (2)	2 (5)	0.162[c]
Decreased	29 (66)	32 (80)	
Increased	14 (32)	6 (15)	
Change in HR, mean			
1st hour	3.1 ± 9.5	4.9 ± 11.4	0.4439[d]
Decreased	16 (36)	13 (32)	0.710[b]
Increased	28 (64)	27 (68)	
6th hour	1.0 ± 8.5	1.1 ± 10.9	0.9634[d]
No change	1 (2)	2 (5)	0.801[c]
Decreased	21 (48)	17 (43)	
Increased	22 (50)	21 (52)	
12th hour	–0.2 ± 8.5	–2.7 ± 9.0	0.1922[d]
No change	2 (4)	1 (3)	1.000[c]
Decreased	25 (57)	24 (60)	
Increased	17 (39)	15 (37)	
Oxygen saturation at 1st hour			
Normal saturation	44 (100)	40 (100)	
Desaturation	0	0	
Oxygen saturation at 6th hour			
Normal saturation	44 (100)	40 (100)	
Desaturation	0	0	
Oxygen saturation at 12th hour			
Normal saturation	44 (100)	40 (100)	
Desaturation	0	0	

[a]Mann Whitney U test; [b]Chi square test; [c]Fisher's Exact test; [d]Independent t test
**Statistically significant based on P value =<0.05*

Table 3. *Adverse effects: butamirate citrate vs. placebo (n=76)**

	BUTAMIRATE CITRATE (n=42) n (%)	PLACEBO (n=34) n (%)	P VALUE
Nausea	1 (2)	3 (9)	0.319[a]
Drowsiness	0	0	-
Diarrhea	0	0	-
Urticaria	1 (2)	0	1.000[a]

[a]*Fisher's Exact test*
** A total of 76 patients was included in the per-protocol analysis, excluding 8 participants who were withdrawn from the study due to conversion to endotracheal tube and refusal to continue participation.*

DISCUSSION

This study showed that patients given Butamirate citrate pre-bronchoscopy reported significantly lower cough severity on the 1st and 12th hour post-procedure and significantly higher percentage reporting without cough 12hrs post-procedure. There is no significant difference in the systolic blood pressure, heart rate, and occurrence of adverse events between the two groups.

Post-bronchoscopy cough is still a common complication of FOB with an incidence of 10.8% to 55.7% and this could present within 4 hours and up to 48 hours post procedure.[2-4] There are already several studies that address cough during bronchoscopy but few studies that focuses on post-bronchoscopy cough.[4] In our practice, we utilize general anesthesia with the use of propofol, midazolam, opioids, muscle relaxants and instillation of lidocaine endobronchial to inhibit the cough reflex during the procedure. General anesthesia provided a peaceful procedure for the bronchoscopists, less anxiety to the patient, inhibition of cough and less desaturations with similar experience to the study of Rafaat et al. which compared general anesthesia versus local anesthesia with conscious sedation.[11] However, this does not address the postprocedural cough that the patient might experience after FOB.

In a study by Scwarz et al., they investigated the benefits of dextromethorphan, a centrally acting antitussive, and found out that it significantly reduces cough within 6 hours and up to the next morning after the procedure.[5] This is not, however, available in our locality. A similar centrally acting antitussive that is safe, affordable, and readily available with a long elimination half-life of 13 hours is butamirate citrate. It is structurally not related to opioids and non-sedating. It also exerts non-specific anticholinergic and bronchodilator effects.[6-9] We believe this is the first study to determine if it is safe and efficacious in alleviating pos-bronchoscopy cough based on the cough severity score, patient's discomfort, monitor measurements and adverse effects.

We used the modified cough severity score, derived from the simplified cough score (SCS) developed by the Respiratory Branch of Chinese Medical Association as a tool for evaluating the severity of cough, to assess the impact of cough during recovery of the patient at the 1st, 6th and 12th hour post-procedure as based on the duration of butamirate citrate and this was evaluated by the outcome assessor.[10] The modified cough severity score consists of 4 points where 0=no cough, 1=occasional cough for short periods, 2=frequent cough which interferes with recovery and 3=distressing cough, which seriously affects recovery. The result showed that the severity of cough is significantly lower in butamirate citrate group as compared to the placebo group at the 1st hour (p=0.0291)and 12th (p=0.0366) hour post procedure. Median cough severity is 1 (IQR 1,2) for butamirate citrate group and 2 (IQR 1,2) for placebo at the 1st hour while the median score of butamirate group is 1 (IQR 0,1) compared to placebo 1 (IQR 1,1) at the 12th hour. Patients in the butamirate group had a higher proportion with modified cough severity score of 0 compared to the placebo group and this is statistically significant at the 12th hour.

Patient's discomfort was also assessed using the 11-point Visual Analogue Scale (VAS) where zero indicates satisfied and 10 denotes very discontented.[10] This is further categorized to satisfied for VAS 0-3, slightly discontented for VAS 4-7 and very discontented for VAS 8-10. Based on the results, patients from both butamirate and placebo group were satisfied and there is no significant difference between the two groups. As mentioned, post-bronchoscopy cough is just one of the possible complications. Other complications of bronchoscopy include sore throat, dysphagia, desaturations, bronchospasm, and malaise as enumerated by Leitin et al. and Ni YL et al. in their studies.[2,4] In our institution the anesthetic techniques we use during FOB is total intravenous anesthesia utilizing laryngeal mask airway as our airway device. This provided a peaceful procedure for both the bronchoscopist and patients. Additional medications such as paracetamol and benzydamine hydrochloride throat sprays were also given to reduce throat pain and dysphagia. This could explain that patients who underwent FOB in our institution were generally satisfied with their procedure.

Coughing may stimulate the autonomic nervous system causing an increase in both the heart rate and blood pressure of the patients.[13] Thus, the changes in the heart rate and blood pressures were analyzed between the two groups. The result showed that the heart rate and blood pressure did not differ significantly. This is also similar to the study of Schwarz, et al. which showed there were no significant changes in the heart rate, blood pressure

and even oxygen saturation in patients who received dextromethorphan and placebo.[5] This could possibly be the effect of anesthesia and other medications given to the patient such as paracetamol and benzydamine throat spray that could alleviate discomfort after the procedure.

With regards to the adverse effects, there was no significant difference between the butamirate and placebo group. Based on the study of Learski et al. the incidence of the possible side effects is 0.5 to 1%.6 In our study, only 1 patient presented with nausea (2%) and another with urticaria (2%) in the butamirate group while 3 patients (9%) in the placebo group had nausea. These patients did not require any interventions, and these adverse effects could also be attributed to the side effects of anesthesia.

CONCLUSION

Butamirate citrate is efficacious and safe as a premedication in alleviating post-bronchoscopy cough in patient undergoing FOB under total intravenous anesthesia with controlled ventilation using laryngeal mask airway based on the modified cough severity score, but it does not affect patient's discomfort, heart rate and blood pressure.

LIMITATIONS OF THE STUDY

The study determined only the alleviation of cough up to 12 hours post-bronchoscopy mainly based on the duration of butamirate citrate. Other complications of FOB such as sore throat, bleeding, and pneumothorax were not included in the study. The anesthesia used was the conventional technique in our hospital and this may be different from other institutions.

There is a significant difference in the bronchoscopy procedures, thus, multiple linear regression analysis was performed for the primary outcome to control for the effect of the significant confounder. It was noted that the results were not statistically significant at the 1st (p=0.17, p=0.380), 6th (p=0.10, p=0.569), and 12th (p=0.09, p=0.510) hour.

RECOMMENDATIONS

We recommend the use of butamirate citrate as pre-anesthetic medications of patients scheduled for FOB if not contraindicated such as allergies, concomitant expectorant use, liver, and renal failure. The use of butamirate may be continued up to 48 hours considering post-bronchoscopy cough persist up to 2 days.

For future studies, larger sample sizes are needed to improve statistical power to determine if there is really a non-significant association between bronchoscopy procedures and post-bronchoscopy cough.

ACKNOWLEDGMENT

The author expresses gratitude to his advisers and co-investigators, Dr. Balaoing and Dr. Jacaban, for providing their invaluable guidance and support for this study, the whole research team including his co-fellows, nurses, Ms. Marla Briones, and the participants for giving their time and effort and making the study a success.

FUNDING

This is a self-funded study.

CONFLICT OF INTEREST

The investigators have no conflict of interest to declare.

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