Comparing the Efficacy of "Spray as You Go" Technique Versus Combined Airway Nerve Block and "Spray as You Go" as Topical Anesthesia During Flexible Bronchoscopy; a Double-Blinded Randomized Clinical Trial

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Abstract- Flexible bronchoscopy is employed to diagnose a range of respiratory disorders. Local airway anesthesia is mandatory to facilitate tracheal intubation. It is commonly done by injection of diluted lidocaine through working channel of bronchoscope via Spray-as-you-go (SAYGO) method. Other methods such as airway nerve block (ANB) by direct injection of lidocaine are also used to increase patient comfort. The aim of this study was to compare patient and physician satisfaction during bronchoscopy in two groups receiving SAGO alone versus combination of SAYGO and ANB. In a double-blinded randomized clinical trial, 68 patients undergoing bronchoscopy were divided into two groups. The first group received local anesthesia solely through the SAYGO method, while the second group received a combination of SAYGO and ANB. Both groups received intravenous sedation. The anesthesia level was assessed using Ramsay score. Patient and physician satisfaction with bronchoscopy was evaluated on a numeric scale of 1 to 5. Combination of ANB and SAYGO resulted in significantly higher satisfaction score both in physician [3.4±1.6 and 4.6±0.8] and patients [3.5±1.3 and 4.9±0.4] (P<0.001). Thirteen individuals (38.2%) in the SAYGO and four individuals (11.8%) in SAYGO+ANB experienced a drop in oxygen levels (P=0.023). Additionally, sedation levels (Ramsay sedation scale score) were significantly higher in the first group (4) compared to the second group (3) (P=0.001). Combining ANB with SAYGO resulted in higher patient and physician comfort during bronchoscopy in comparison to SAYGO alone with no increase in complications.

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Keywords: Bronchoscopy; Local anesthesia; Lidocaine; Airway nerve block

Introduction

Flexible bronchoscopy (FB) is generally performed in pulmonary medicine for various diagnostic and therapeutic purposes (1). One of the main issues leading to patient dissatisfaction is coughing caused by irritation of airway mucosa or glottis (2). The key factor in ensuring a smooth and comfortable bronchoscopy procedure is proper administration of local airway anesthetics in combination with sedative drugs. However, many unwanted bronchoscopy complications such as respiratory depression, hypoxemia, cardiac arrhythmia and hemodynamic instabilities are caused by intravenous sedative and analgesic drugs used within the procedure. Therefore, appropriate local airway anesthesia (LAA) is fundamental during safe and optimal FB. Improvement in

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LAA reduces the number of cardiorespiratory events by minimizing the sedative drug dose. Local airway anesthesia includes nasopharyngeal, vocal cords and tracheal anesthesia. Lidocaine is the most commonly utilized drug for topical anesthesia in FB. The "spray-as-you-go" (SAYGO) technique is one of the most commonly used methods to reach vocal cord and tracheal anesthesia. In this technique, lidocaine is administered through working channel of bronchoscope as the operator goes toward vocal cords and then trachea. In the 1990s, initial experiments on the SAYGO technique for diagnostic bronchoscopy were documented (3-6). This approach offers the advantage of providing optional and repetitive airway anesthesia, thus enhancing flexibility during the procedure. However, glottis and tracheal anesthesia can be done by trans-cricoid injection of lidocaine or laryngeal nerve block. There are reports that techniques including trans -cricoid injection of lidocaine (TCL) and laryngeal nerve block had great success in patient satisfaction by exerting appropriate local anesthesia and might be superior to SAYGO alone with less cumulative dose of administered lidocaine (7-10).

However, considering the advent of technology and progresses in diagnostic and therapeutic bronchoscopy, the studies to find the most suitable anesthetic technique are lacking behind. There are only a few reports of combination SAGO and ANB technique.

In this study, it was aimed to compare patient and operator satisfaction between two groups undergoing FB; one group receiving LAA with SAYGO technique and the second one receiving ANB block in addition to SAYGO technique.

Materials and Methods

Ethical consideration

All patients' information was confidential. Ethical declarations of the Helsinki and Ethics Research Committees affiliated with Tehran University of Medical Sciences were considered. The study was conducted after approval by the Research Council of the Medical School, Tehran University of Medical Sciences and receiving the code of ethics (IR.TUMS.IKHC.REC.1397.122) and registration on the Iranian registry of clinical trials (IRCT20130210012419N3). The patients were informed about study aims and design. The risks of local anesthesia and nerve block were described for them. The pulmonologist assistant communicated the patients and obtained informed consent. (https://en.irct.ir/trial/34280)

Patients

This double-blinded randomized clinical trial study was performed on patients who were referred for elective diagnostic flexible bronchoscopy to Imam Khomeini hospital affiliated with Tehran University of Medical Sciences. The recruitment date started from 2018-12-21. Senior pulmonologist consultant selected and recruited the patients. She was independent to the study assessment and clinical care. The inclusion criteria consisted of patients aged between 18 and 95 years, with clinical indications necessitating diagnostic flexible bronchoscopy, bronchoscopy with Broncho Alveolar Lavage (BAL), endobronchial biopsies (EBBX), and Trans Bronchial Lung Biopsy (TBLB). Exclusion criteria encompassed patients who did not provide consent, had allergies to any of the study drugs (including midazolam, fentanyl, propofol, and lidocaine), were pregnant, had coagulation disorders, or were using anticoagulants such as heparin, warfarin, direct thrombin inhibitors, etc. Patients with stridor or hemodynamic instability were also excluded from the study.

Sample size

According to the study done by Hamad S *et al.*, (9), the sample size in each group was determined to be at least 30 subjects (power of 0.8, type-1 error of 0.05, and dropout rate of 15%).

$$n = \frac{\left(z_1 - \frac{\alpha}{2} + z_1 - \beta\right)^2 (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}$$

μ_1=6	Z (1-α/2)=1.96
μ_2=2.4	Z (1-β)=0.84
σ_1=5.8	
σ_2=3	N=30

Randomization and allocation concealment

Randomization was conducted using the Quadruple number block method. All patients received intravenous sedation administered by an individual anesthesiologist. To ensure consistency, small opaque adhesive tape was applied to the nerve block injection sites, irrespective of whether the injection was actually administered or not. Operator satisfaction was assessed by a blinded nurse upon the completion of bronchoscopy. Similarly, another blinded nurse from the patient's group assessed patient satisfaction after they had fully regained consciousness in the recovery room. The mentioned nurse recorded the delayed complications of lidocaine, such as convulsion. All patients were monitored in recovery room for at least two hours.

Procedures

In both groups, the SAYGO technique was utilized during bronchoscopy procedures. Both groups received sedation via intravenous injection of midazolam, and if necessary, fentanyl or propofol. All bronchoscopies were conducted through the mouth, and a 10% lidocaine spray was used to anesthetize the oropharyngeal structures in all patients. An individual pulmonologist (experience >5 years) performed all the procedures. She was blinded to the patients' group. Vital signs were monitored and recorded before, during, and after bronchoscopy. Continuous pulse oximetry was employed during the procedure, and a drop in oxygen saturation below 90% (SPO2 <90%) was considered as desaturation.

In the SAYGO group (group S), local anesthesia was administered solely through the working channel of the bronchoscope, with direct visualization of lidocaine application on the vocal cords (4 mL), right main bronchus (2 mL), and left main bronchus (2 mL). An additional 2 mL bolus of lidocaine 2% was given if needed.

The second group (group SB) received airway Nerve Block in addition to first group interventions. This involved injecting 3 ml of 1% lidocaine at the cricothyroid membrane site for recurrent laryngeal nerve block, and injecting 1.5 mL of 1% lidocaine on both sides of the neck at the hyoid horn site for superior laryngeal nerve block. An individual anesthesiologist (experience >5 years) performed all nerve blocks in bronchoscopy room 5 to 10 minutes before the procedure.

The patients and operator rated their satisfaction using numerical scoring system 0 to 5, where 0 was no satisfaction and 5 was complete satisfaction.

Data analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS), version 24, for Windows (SPSS Inc., Chicago, IL). Frequency was used to express qualitative variables, while mean and standard deviation were used for quantitative variables that exhibited normal distribution. Median (interquartile range) was employed for non-normally distributed variables. T-test was utilized to compare quantitative variables between two groups, while chi-square test was employed for qualitative comparisons. A level of $P \leq 0.05$ was considered statistically significant. Graphing was done using Graph Pad Prism version 9.5.1 for Windows (Graph Pad Software, Boston, Massachusetts USA, www.graphpad.com).

Results

Among 70 patients who were assessed for eligibility, two patients refused to consent. Finally,68 patients were assigned into two groups of 34 people (Figure 1, supplement). There were no significant differences between two groups in terms of age and gender, as reported in Table 1.

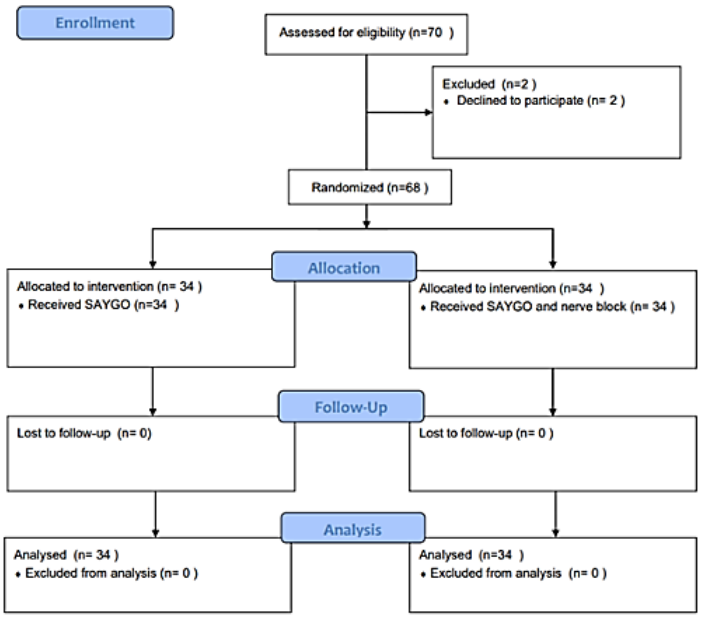

Figure 1. Consort flow diagram of trial

Table 1. Demographic profiles of patients

Items		Frequency (Percentage)		*P*
		S	SB	
Gender (M/F)	**Male**	21(61.8%)	22(64.7%)	0.801
	Female	13 (38.2%)	12(35.3%)	
Age(y)	**Mean**	S	SB	0.623
	±Std. Deviation	52.26±15.57	50.32±16.81	

Reasons for bronchoscopy, complications and Ramsay sedation score are shown in table 2. The reasons did not differ between study groups (*P*=0.096). None of the patients in both group developed lidocaine overdose complications such as convulsion. Moderate bleeding developed in 2 patients, one occurring in the S group and another in the SB group, both of which were effectively controlled using argon plasma coagulation. Additionally, one case of pulmonary edema was recorded in the S group. However, these findings did not demonstrate statistical significance (*P*=1.00). Median Ramsay sedation scale score was 4 (IQR 3-4) and 3 (IQR 2-3) in groups S and SB, respectively. The difference was found to be significant (*P*=0.001) (Figure 2).

Thirteen patients (38.2%) in the S group and 4 patients (11.8%) in the SB group suffered a decrease in oxygen saturation during bronchoscopy (*P*=0.023) (Figure 3). Patients' satisfaction was 3.5±1.3 and 4.9±0.4 in the S and SB groups, respectively (*P*<0.001). Similarly, operator's satisfaction was 3.4±1.6 and 4.6±0.8 in the S and SB groups, respectively, which was statistically different (*P*<0.001) (Figure 4).

Table 2. Bronchoscopy data

Reasons for bronchoscopy										
Variables	**Bronchoscopy + BAL**		**EBB**		**Flexible bronchoscopy without sampling**		**Hot biopsy**		**TBLB**	
Group	S	SB	S	SB	S	SB	S	SB	S	SB
Frequency	12	10	19	12	1	8	1	2	1	2
Percentage	35.3%	29.4%	55.9%	35.3%	2.9%	23.5%	2.9%	5.9%	2.9%	5.9%

Bronchoscopy complications (bleeding and pulmonary edema)			**Sedation level (Ramsay sedation score)**					
Group	**Frequency (percentage)**			**Frequency (percentage)**				
	Yes	No	Level	1	2	3	4	5
S	2 (5.9%)	32(94.1%)	S	1(2.9%)	5(14.7%)	10(29.4%)	13(38.2%)	5(14.7%)
SB	1(2.9%)	33(97.1%)	SB	6(17.6%)	3(8.8%)	22(64.7%)	2(5.9%)	1(2.9%)

BAL, Broncho alveolar lavage; EBBX, Endo bronchial biopsy; TBLB, Trans bronchial lung biopsy; S, Spray-As-You-Go; SB, Spray-As-You-Go plus nerve block

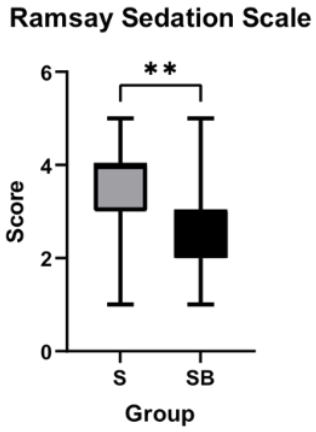

Figure 2. Ramsay sedation scale score between the two study groups

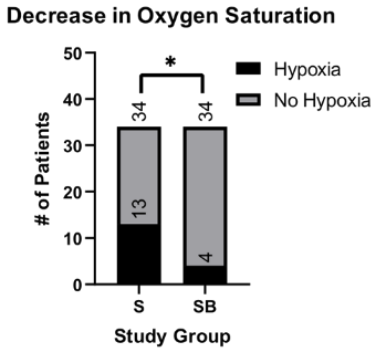

Figure 3. Drops in oxygen saturation across study groups

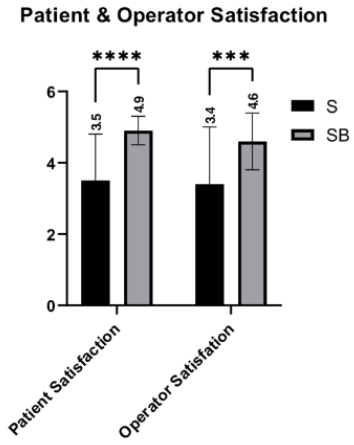

Figure 4. Patient and operator satisfaction

Discussion

The primary objective of this study was to compare patient and operator satisfaction during flexible diagnostic bronchoscopy between two groups of ANB plus SAYGO and SAYGO alone. The results showed that joint technique of ANB plus SAYGO leads to enhanced patient and operator satisfaction, reduced numbers of desaturation, and optimal sedation compared to SAYGO alone. The results are consistent with previous studies,

highlighting superior efficacy of ANB method; in 2011, Chandra *et al*., showed that TCL was superior to SAYGO technique in terms of cough episodes, time to reach carina and cumulative dose of lidocaine. But, in their study, only the patients needed broncho- alveolar lavage were included (11). Similarly, Hamad et al. in a single-blinded study showed that TCL was a safe and effective adjunct to local anesthesia during flexible bronchoscopy. They reported that ease of procedure and cough frequency significantly improved by adjunctive technique (9). Madan *et al*., in a randomized trial in 2019 compared the operator satisfaction, cough severity and lidocaine cumulative doses between two groups; TCL vs. SAGO. They also found that TCL was superior in terms of cough severity, operator satisfaction and cumulative lidocaine dosage (10). In a systematic review published in 2021, Madan *et al*., showed TCL is a preferred technique for local anesthesia during bronchoscopy. TCL showed advantage in greater operator satisfaction, less cough and reduced cumulative dose of lidocaine (12). There are reports demonstrating the benefits of TCL adjunct in local airway anesthesia beyond fiber-optic diagnostic bronchoscopies. Endobronchial-ultrasonography (EBUS) procedure was shown to be performed more evenly by TCL in comparison to SAYO (13).

In a clinical trial conducted by Mathur *et al*., the efficacy of local anesthesia for awake naso-tracheal intubation was compared between two groups of patients scheduled for surgery. In one group, lidocaine was administered via jet nebulizer; while the remaining received ANB. Airway nerve block technique was so similar to our study; involving bilateral superior laryngeal nerve block and trans-cricoid injection. The results indicated that ANB improved time consuming and patient comfort for intubation (14). Khandelwal *et al.*, designed a random study on patients requiring awake fiber-optic intubation. They evaluated the effect of adjunct lidocaine to ANB on patient's comfort; the results were consistent with previous results and showed more patient comfort in adjunct technique (15).

Literature reviews shows there is few study against ANB to achieve local airway anesthesia. In addition, optimal delivery route of lidocaine into airways remains to be exactly defined.

There were limits in our study. The procedures were only for diagnostic purpose. The study sample was not large enough to add another group receiving just TCL not superior laryngeal block. Blood level and cumulative dose of lidocaine were not measured. Further studies with larger patient populations are needed to address those limits.

The findings of this study indicate that the addition of airway nerve block as a supplement to the SAYGO method is safe and effective in improving the ease of bronchoscopy for both patient and operator satisfaction; the resulted airway anesthesia precludes higher dose of sedatives and deep sedation levels.

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