The Laryngoscope

Shikani Optical Stylet for Awake Nasal Intubation in Patients Undergoing Head and Neck Surgery

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Objectives: To evaluate the efficacy and safety of the Shikani optical stylet (SOS) versus fiberoptic bronchoscope (FOB) for awake nasal intubation in head and neck surgery patients with an anticipated difficult airway.

Study Design: Prospective randomized clinical trial.

Methods: This study involved 50 adult patients scheduled for elective head and neck surgery and presented with an anticipated difficult airway. Patients planned for awake nasotracheal intubation were randomly divided into two groups: FOB (n = 25) and SOS (n = 25). Patients were intubated under local anesthesia and sedation using the randomly assigned intubation device by anesthetists proficient in both airway devices. The time to successful intubation was regarded as the primary endpoint.

Results: The median time (interquartile range) to tracheal intubation in the FOB group was 74 seconds (57–108) and 38 seconds (27–60) in the SOS group ($P < .001$). Intubation success rates on the first attempt in the FOB and SOS groups were 96% and 92%, respectively ($P > .999$). Airway assisted maneuvers were required in six (24%) SOS intubations compared to 21 (84%) FOB intubations ($P < .001$). There were no significant differences between the groups in the incidences of oxygen desaturation and postoperative complications related to intubation.

Conclusion: Compared to the FOB group, awake nasal intubation in the SOS group required significantly less time and fewer airway-assisted maneuvers on adult head and neck surgery patients with anticipated difficult airway.

Key Words: Shikani optical stylet, awake nasal intubation, fiberoptic intubation, difficult airway, head and neck surgery.

Level of Evidence: 2

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INTRODUCTION

Management of difficult airway is one of the greatest challenges for anesthesiologists. It is estimated that more than 30% of anesthesia-related deaths are associated with hypoxia, which is frequently caused by failed, difficult, or delayed intubation.[1] The safest method of intubation is to place the tracheal tube in an awake, spontaneously breathing patient.[2] Therefore, awake intubation is widely advocated for management of anticipated difficult airway.[3] Airway management in head and neck surgery patients demands special focus.[4] Patients undergoing head and neck surgery frequently present with difficult airway due to known or suspected anatomical and/or physiological difficulties, including facial malformation, restricted head and neck movement, obstructive mass, previous radiotherapy, limited mouth-opening, or associated comorbidities.[5] Meanwhile, head and neck surgeries usually require nasal intubation, which allows leeway for operative maneuvering in the mouth, pharynx, larynx, and neck. Hence, awake nasotracheal intubation is considered as a preferred strategy for patients undergoing head and neck surgery with predicted difficult airway.

To manage patients with predicted difficult airway, the choice of highly safe and effective intubation devices is crucial. The fiberoptic bronchoscope (FOB) is the gold standard and the most commonly used tool for awake intubation. However, disadvantages including difficult maneuvering and advancing the tube, extensive training, instrument damage, and costly repair limit the availability of FOB in awake intubation.[6,7] Therefore, alternatives to FOB for accomplishing awake nasal intubation are needed.

The Shikani Optical Stylet (SOS) (Clarus Medical, Minneapolis, MN) is a malleable, J-shaped stylet and has illumination fibers that are used with a camera or its optical lens. The SOS has an adjustable tube stop, an oxygen insufflation port, and can accommodate any endotracheal tube with a size greater than 5.5 mm interior diameter (ID). For patients under general anesthesia, the SOS is an acceptable alternative to laryngoscopic intubation.[8-10] Moreover, the SOS has been shown to more effectively reduce intubation time as compared with FOB in patients undergoing awake oral intubation.[11] However,

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the use of SOS for awake nasal intubation in patients under local anesthesia and sedation has not been explored. Thus, the present randomized clinical trial (RCT) evaluated the efficacy and safety of SOS in adult patients undergoing head and neck surgery for awake nasal intubation.

MATERIALS AND METHODS

Ethical approval for the present RCT was provided by the Peking University Hospital of Stomatology Ethics Committee (no. PKUSSIRB-201942017). The study was registered at www.chictr.org.cn (no. ChiCTR1900021515), and informed written consent was obtained from all included patients before the study.

Participants

Potential study participants were assessed based on the inclusion criteria a day before surgery. The RCT included patients scheduled for head and neck surgery, aged 18 to 65 years, required nasotracheal intubation, and presented with an anticipated difficult airway. Two anesthesiologists conducted airway assessments according to the predictive score of difficult intubation described by Arné et al.[12] (Table I). Patients were excluded based on the following criteria: 1) American Society of Anesthesiologists (ASA) class ≥ III; 2) contraindication for nasal intubation; 3) uncooperative or mentally unstable patients.

Randomization

Randomization was conducted via a computer-generated random number table allocation and sealed in an envelope by one of the authors (L.J.), who was blinded to patient recruitment and data collection. Following randomization, patients were assigned to awake nasal intubation with either the SOS or FOB. Patients in the SOS group were intubated by SOS, whereas FOB group patients were intubated using FOB (11302BDX, Karl Storz, Tuttlingen, Germany).

TABLE I
Predictive Risk Index for Difficult Intubation.

Risk Factors	Points
Previous knowledge of difficult intubation	No, 0; Yes, 10
Pathologies associated with difficult intubation	No, 0; Yes, 5
Clinical symptoms of airway pathology	No, 0; Yes, 3
Inter-incisor gap and mandible luxation	IG ≥5 cm or ML > 0, 0
	3.5 cm < IG < 5 cm and ML = 0, 3
	IG < 3.5 cm and ML < 0, 13
Thyromental distance	≥ 6.5 cm, 0
	< 6.5 cm, 4
Maximum range of head and neck movement	Above 100°, 0
	About 90° (± 10°), 2
	Below 80°, 5
Modified Mallampati classification	Class 1, 0
	Class 2, 2
	Class 3, 6
	Class 4, 8
Maximum score	48

7 ≤ score < 11: moderate risk of difficult intubation; score ≥ 11: high risk of difficult intubation.
IG = inter-incisor gap; ML = mandible luxation.

Intubation and Anesthesia

Patients were taken to the operating room (OR) without any premedication. In the OR, electrocardiogram monitoring was done along with assessment for noninvasive blood pressure, pulse oxygen saturation, respiratory rate, and capnography. Subsequently, an intravenous catheter was inserted and 1.0 mg midazolam was administered. Then, dexmedetomidine was administered for 10 minutes at a 0.5 to 1.0 μg/kg loading dose and continually infused at 0.2 to 0.7 μg/kg/hour. Patients received target-controlled infused remifentanil 1.0 to 3.0 ng/mL before intubation. The anesthetist determined the specific dose according to the patient's response. Otherwise, if needed, a propofol bolus dose of 10 to 20 mg was intravenously administered to induce patient sedation equivalent to a Ramsay score of 2 through 4.

For topicalization, a lidocaine aerosol delivering 16 mg lidocaine per spray was directly applied to the mucosa of the oropharynx and the surface of the tongue. Lidocaine 2% gel and ephedrine were used to lubricate the lower nasal duct. Next, 2 ml of 20 mg tetracaine was administered via a transtracheal injection.

Adequate preoxygenation (end-tidal oxygen concentration greater than 90%) was ensured by administering patients with 6 L/minute of oxygen using a mask. Nasotracheal intubation was achieved using a preformed double-curved nasotracheal tube (Shiley RAE Nasal, Covidien, Ireland), 7.0 mm ID and 6.5 mm ID for male and female patients, respectively. Patients in both the FOB and SOS groups were intubated by the attending anesthetists, who had more than 5 years of experience in anesthesia and nasotracheal intubation.

In the FOB group, the "scope-first" technique was used for intubation. A nasotracheal tube lubricated with liquid paraffin was loaded onto the FOB. Once the tip of the FOB was inserted into the trachea, the tube was advanced into the trachea along with the FOB. The FOB was then withdrawn as the tube was held in place. For intubation with SOS, a lubricated nasotracheal tube was mounted onto the stylet. The stylet-tube assembly was then inserted into the nostril with the anteriorly curved part of the stylet and advanced at a sharp angle into the nasal cavity and the nasopharynx. Once the glottis was viewed, the tube was advanced over the stylet into the trachea. Successful tracheal intubation was confirmed by capnography. In case a technique was tried for more than 10 minutes or failed thrice, a switch to the other technique was made.

Definitions of Outcomes

The primary endpoint was the total time for intubation, defined as the duration from when the device tip entered the nostril to when the tube entered the trachea, as confirmed by capnography. The secondary endpoints included the time for device and tube insertion: The time for device insertion was defined as the duration from when the device tip entered the nostril to when it passed through the vocal cord; the time for tube insertion was defined as the duration from when the tip of the device passed through the vocal cord to when the tube was confirmed inserted into the trachea. Other secondary endpoints included the total success rate, intubation success on first attempt, necessity for assisted maneuvers including movement of the jaw and/or head position during intubation, necessity for tube

TABLE II
Severity of Epistaxis During Intubation.

Severity	Definition
None	No blood observed on either the surface of the tube or posterior pharyngeal wall
Mild	Blood apparent on the surface of the tube or posterior pharyngeal wall
Moderate	Pooling of blood on the posterior pharyngeal wall
Severe	Large amount of blood in the pharynx impeding nasotracheal intubation and necessitating urgent orotracheal intubation

rotation to facilitate tube passage through the intubated device into the trachea, hemodynamic parameters during intubation, as well as incidence and severity of epistaxis. Epistaxis was recorded using the criteria described by Sugiyama et al.[13] (Table II). Further, intubation-related postoperative complications such as nasal obstruction, epistaxis, pain, and sore throat were recorded.

Other Data Collection

Baseline and preoperative data included demographic characteristics (age, sex, and body mass index), medical history, ASA physical status classification, clinical laboratory data, heart rate (HR), blood pressure before surgery, and airway evaluation. Intraoperative data included information on sedative and analgesic drugs used during intubation.

Hypothesis Statement and Calculation of Sample Size

The primary hypothesis was that the time for awake nasal intubation differs significantly between SOS and FOB. A previous study estimated the mean (standard deviation [SD]) time for awake nasal intubation using FOB in patients with oropharyngeal tumor at 90.25 (9.41) seconds.[14] Based on this result, the sample size required to detect a 10% reduction in intubation time, at a significance level of 0.05 and a power of 0.9, is 23 patients per group. Considering a loss to follow-up rate of about 10%, we designed to enroll 25 patients per group. The sample size was calculated using PASS 11.0 software (NCSS Statistical Software, East Kaysville, UT).

Statistical Analysis

Normally distributed quantitative data were expressed as mean ± SD, and quantitative data with abnormal distribution were represented using the median and interquartile range (IQR). Categorical data were presented as a percentage. The *t* test was used for comparison of normally distributed variables among groups. A comparison of numeric data with abnormal distribution was made using the Mann–Whitney *U* test. Qualitative variables were compared using either the chi-square or Fisher

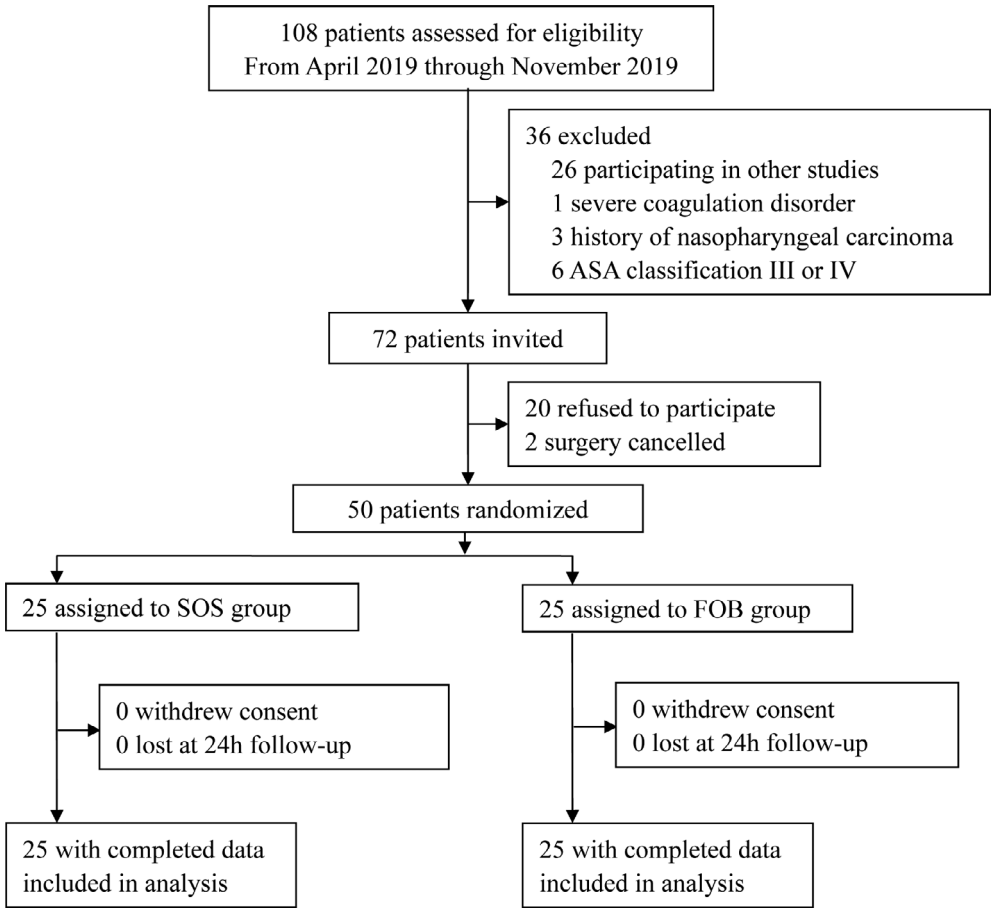

Fig. 1 Flowchart of trial.

exact test. Ranked data were compared by the rank-sum test. For all statistical tests, two-sided $P < .05$ was regarded as statistically significant. All statistical analyses were performed with SPSS software v24.0 (IBM, Armonk, NY).

RESULTS

The present RCT was conducted from April 2019 through November 2019 and included 50 subjects: 25 in the SOS group and 25 in the FOB group. All 50 patients met the inclusion criteria. A flowchart of the trial is presented in Figure 1.

There were no significant differences in the demographic and preoperative characteristics of patients in the two groups (Table III). Median intubation time with FOB was 74 seconds (IQR 57–108), and with SOS was 38 seconds (IQR 27–60) ($P < .001$). Both the time for device and tube insertion in patients intubated by SOS were significantly shorter than those by FOB. Intubation was successfully performed in all patients, and intubation success rates on the first attempt were 96% versus 92% for FOB and SOS groups, respectively ($P > .999$). More FOB patients needed tube rotation during tube insertion to facilitate intubation than SOS patients (3 [12%] with SOS vs. 17 [68%] with FOB, $P < .001$). We also found that intubation by FOB had more assisted maneuvers than with SOS (6 [24%] with SOS vs. 21 [84%] with FOB, $P < .001$). The incidence of body resistance or movement during intubation was comparable between the two groups. No severe bleeding occurred during our study, and the incidence of epistaxis during intubation was not significantly different between the groups (Table IV).

In addition, there were no significant differences between the two groups with regard to the hemodynamic parameters of blood pressure and heart rate. Although the quantities of remifentanil and propofol used in the two groups were not significantly different, SOS patients

TABLE III
Baseline Characteristics and Preoperative Evaluation Data.

	SOS (n = 25)	FOB (n = 25)	*P* Value
Age (years)	45 ± 10	40 ± 13	.166
Male	17 (68.0%)	15 (60.0%)	.769
BMI (kg/m^2)	21.8 ± 3.5	21.1 ± 3.7	.479
BMI > 24 (kg/m^2)	6 (24.0%)	7 (28.0%)	>.999
Airway evaluation			
Score of DI	21 (25, 31)	25 (21, 27)	.460
Previous knowledge of DI	5 (20.0%)	2 (8.0%)	.417
Pathologies associated with DI	3 (12.0%)	6 (24.0%)	.463
Clinical symptoms of airway pathology	3 (12.0%)	5 (20.0%)	.702
Thyromental distance (cm)	6.3 ± 0.7	6.3 ± 0.6	.668
Head and neck movement ≤ 100°	6 (24.0%)	4 (16.0%)	.725
Modified Mallampati classification			>.999
Class 3	2 (8.0%)	2 (8.0%)	
Class 4	23 (92.0%)	23 (92.0%)	
ASA physical status classification			.156
Grade 1	9 (36.0%)	15 (60.0%)	
Grade 2	16 (64.0%)	10 (40.0%)	
Admission vital signs*			
HR (bpm)	79 ± 15	77 ± 13	.681
SBP (mmHg)	129 ± 13	126 ± 17	.489
DBP (mmHg)	78 ± 9	75 ± 10	.235
MAP (mmHg)	95 ± 9	92 ± 12	.287
SpO_2 (%)	98 ± 1	98 ± 1	.804

*Vital signs when admitted to the operation room.
ASA = American Society of Anesthesiologists; BMI = body mass index; DBP = diastolic blood pressure; DI = difficult intubation; FOB = fiberoptic bronchoscope; HR = heart rate; MAP = mean arterial pressure; SBP = systolic blood pressure; SOS = Shikani optical stylet; SpO_2 = pulse oxygen saturation.

TABLE IV
Trial Outcomes.

	SOS (n = 25)	FOB (n = 25)	*P* Value
Intubation time (s)	38 (27, 60)	74 (57, 108)	< .001
Device insertion time (s)	31 (20, 50)	45 (34, 56)	.020
Tube insertion time (s)	8 (4, 12)	20 (14, 31)	< .001
Total success rate	25 (100.0%)	25 (100.0%)	> .999
First-attempt success	23 (92.0%)	24 (96.0%)	> .999
Rotation of the tube	3 (12.0%)	17 (68.0%)	< .001
Assisted maneuvers*	6 (24.0%)	21 (84.0%)	< .001
Body resistance or movement	5 (20.0%)	6 (24.0%)	> .999
Epistaxis during intubation			.677
None	16 (64.0%)	14 (56.0%)	
Mild	7 (28.0%)	10 (40.0%)	
Medium	2 (8.0%)	1 (4.0%)	
Severe	0 (0.0%)	0 (0.0%)	

*Including movement of the jaw and/or head position.
FOB = fiberoptic bronchoscope; SOS = Shikani optical stylet.

TABLE V
Hemodynamic Parameters, Drugs, and Ramsay Sedation Score During Intubation.

	SOS (n = 25)	FOB (n = 25)	*P* Value
Hemodynamic parameters			
Highest HR (bpm)	75 ± 16	80 ± 17	.290
Lowest HR (bpm)	66 ± 14	66 ± 14	.984
Highest SBP (mmHg)	132 ± 20	130 ± 22	.792
Lowest SBP (mmHg)	112 ± 15	110 ± 17	.568
Highest DBP (mmHg)	79 ± 10	78 ± 13	.817
Lowest DBP (mmHg)	69 ± 10	69 ± 10	.989
Highest MAP (mmHg)	96 ± 12	95 ± 15	.792
Lowest MAP (mmHg)	83 ± 11	82 ± 11	.778
Lowest SpO_2 (%)	98 (97, 99)	97 (93, 98)	.015
Drugs			
Remifentanil (μg)	84 ± 18	77 ± 21	.183
Dexmedetomidine (μg)	58 ± 12	50 ± 15	.041
Propofol (mg)	22 ± 9	19 ± 10	.271
Ramsay sedation score	3 (2, 4)	3 (3, 4)	.561

bpm, beats per minute; DBP = diastolic blood pressure; FOB = fiberoptic bronchoscope; HR = heart rate; MAP = mean arterial pressure; SBP = systolic blood pressure; SOS = Shikani optical stylet.

TABLE VI
Adverse Events.

	SOS (n = 25)	FOB (n = 25)	*P* Value
Desaturation			
$SpO_2 \leq 90\%$	2 (8.0%)	4 (16.0%)	.667
$SpO_2 \leq 85\%$	2 (8.0%)	1 (4.0%)	>.999
Postoperative complications	11 (44.0%)	8 (32.0%)	.561
Continuous epistaxis	4 (16.0%)	3 (0.0%)	>.999
Pain of the nose	3 (12.0%)	1 (4.0%)	.609
Sore throat	10 (40.0%)	8 (32.0%)	.769
Nasal obstruction	2 (8.0%)	2 (8.0%)	>.999
Severe damage of airway	0 (0.0%)	0 (0.0%)	

FOB = fiberoptic bronchoscope; SOS = Shikani optical stylet; SpO_2 = pulse oxygen saturation.

received a higher dosage of dexmedetomidine. The Ramsay sedation scores of the two groups were comparable (Table V).

With regard to intubation-related complications, the incidence of hypoxemia during intubation was comparable between the two groups (Table VI). Oxygen saturation in two FOB patients and four SOS patients fell below 90% ($P = .667$). One FOB patient and two SOS patients experienced oxygen saturation that fell below 85% ($P > .999$). Incidence of intubation-related complications within 24 hours postoperation was comparable between the two groups. No severe airway injury occurred. Sore throat was the most prevalent postoperative complication, detected in 10 SOS patients (40%) and 8 FOB patients (32%) ($P = .769$). Otherwise, the occurrence rates of continuous epistaxis, pain in the nose, and nasal obstruction were not significantly different between the two groups (Table VI).

DISCUSSION

Optimal airway management is critical in patients undergoing head and neck surgery. Awake nasotracheal intubation is an important strategy for the management of the difficult airway in such patients. Although FOB is probably most commonly used in awake nasal intubation, disadvantages limit its practice. Therefore, it is necessary to look for alternatives. Case reports have described the efficacy and safety of SOS in difficult airway management.[15,16] Previous trials have compared the efficacy and safety of SOS to Macintosh laryngoscope and FOB in patients with anticipated difficult airway.[10,11] However, these studies were conducted in patients under oral intubation. Notably, nasotracheal intubation is technically different from orotracheal intubation. Although no study has explored the use of SOS for nasal intubation, two clinical trials reported that Trachway (Biotronic Instrument Enterprise Ltd., Tai-Chung, Taiwan, China), a rigid optical stylet similar to SOS, is superior to FOB for nasal intubation in patients under general anesthesia.[17,18] To date, however, no RCT has compared the use of SOS to FOB for awake nasal intubation in patients with identified difficult airway. Our results suggest that in patients who underwent head and neck surgery with an anticipated difficult airway, awake nasal intubation by SOS has similar success rates to FOB but takes a significantly shorter time to perform than FOB. Moreover, the procedure does not lead to additional adverse effects.

During awake intubation, a prolonged intubation time can be precarious, particularly in patients who are at increased risk of loss of airway patency due to sedative and analgesic drugs. Moreover, decreased intubation time shortens duration of the stressful procedure in awake, albeit sedated, patients. Therefore, reduction in intubation time is also closely related to less patient discomfort. In our study, the SOS group had a median successfully intubation time that was 36 seconds shorter than the time of intubation with the FOB. Although whether this difference on intubation time is truly relevant is debatable, previous studies considered 30 seconds as a clinically relevant difference in awake endotracheal intubation.[19,20] Hence, the difference of 36 seconds may potentially have clinical significance for patients under awake nasal intubation.

FOB is flexible and therefore more difficult to maneuver. Our results indicated that the time of device insertion was significantly longer in the FOB group than in the SOS group. The rigid structure of SOS facilitates better maneuverability during navigation to the glottis. Meanwhile, SOS has several unique characteristics that make it suitable for nasal intubation. For instance, SOS can be advanced together with the tracheal tube and allows an all-way optical intubation by visualizing the anatomy. Second, the rigid SOS stylet provides guidance while inserting through the nasal cavity and vocal cord, and the levering effect of SOS facilitates advancement of the stylet and tube. Thus, for awake nasal intubation, the SOS takes less time to navigate to the glottis than the FOB. Additionally, compared with SOS, FOB demands more assistance from a nurse or a second anesthetist to enhance the fiberoptic view or facilitate tube insertion.

Tube passage is also more challenging when using FOB.[21-23] During nasotracheal intubation with FOB, the tube is blindly advanced through the nasal cavity and makes a sharp angle from the nasopharynx into the oropharynx. Thus, FOB has poor guidance and tends to sway during tube insertion such that difficulties in advancing the tracheal tube over the fiberscope are frequently encountered during fiberoptic intubation.[22] Successful attempts usually require tube retraction and more tube rotation.[24,25] In our study, 68% of patients needed tube rotation to facilitate FOB intubation, which increases patient discomfort. Moreover, the blind advancement of the tracheal tube over FOB could cause traumatic laryngeal injury and pneumomediastinum.[26,27] When using SOS, however, the tracheal tube is directly preloaded on the optical stylet. Once the glottis is viewed, the tube can be advanced over the stylet into the trachea. This observation was validated by our finding that intubation using SOS consumed less time during tube insertion and required less assistance for tube rotation. Thus, SOS likely provides a faster option and reduces the occurrence of injuries caused by blind insertion.

The total success rate and first-attempt success rate in our study were high, and no significant differences in

the two rates were recorded between the groups. Three failed first attempts were either due to the presence of nasal secretions or a blood-stained lens that prevented adequate vision, and all succeeded after wiping the lens. The high success rate could be attributed to the fact that the anesthetists in our study are well skilled in managing difficult airway and in both SOS and FOB techniques. Poor skills may lead to failed intubation and airway injury in management of difficult airway. Because the awake nasal intubation is a high-risk procedure, especially in patients presenting head and neck pathologies, the awake nasotracheal intubation should not be attempted by inexperienced operators.

In terms of operator training of SOS-assisted intubation, studies have demonstrated that SOS is a simple and effective device, and proficiency can be achieved with minimal tuition in routine or difficult orotracheal intubation.[28,29] Moon et al.[30] evaluated the learning curve of a rigid optical stylet similar to SOS in inexperienced practitioners and found that only 10 intubation experiences were sufficient to achieve competency. However, as of this writing, no published studies have reported training of SOS-assisted nasal intubation. In our study, anesthetists' skills in applying intubation devices were gained through "on-the-job" experiential learning. The rigid nature and all-way optical characteristic demonstrated that SOS-assisted nasal intubation appears to be a facile procedure and may require relatively fewer attempts to achieve proficiency than other intubation techniques. Moreover, the short time required for intubation may also provide information about the simplicity of the technique. During SOS training, one of the main issues we encountered that led to failed intubation was an obscured optical view caused by excessive secretions or blood. Therefore, adequate nasal preparation, appropriate aspiration of the nasopharynx and oropharynx, and an antifogging agent to the lens tip are strongly recommended during training of inexperienced operators. In addition, early training may be enhanced through use of intubation manikins to gain familiarity with the anatomy and SOS instrument. Finally, to better understand the learning curve and concerns for training of nasal intubation using SOS in management of the difficult airway, well-designed prospective studies are warranted.

Awake intubation is frequently associated with severe hemodynamic responses and results in complications. Mahrous et al.[11] explored the hemodynamic response of SOS and the FOB for awake oral intubation and reported no significant differences in mean arterial pressure and HR between the patients intubated using the two methods. Although our study recorded a slight increase in the HR and blood pressure during intubation, we did not observe significant differences in hemodynamic parameters between the two groups. However, patients in the SOS group received a higher dose of dexmedetomidine than the FOB group. This finding may be due to the rigid nature of SOS. Although most patients tolerated the intubation, slight body movements were noted in some patients; however, there were no differences in body movement frequency between the two groups.

The present study showed that the incidence of FOB- or SOS-related severe complications was minimal. Whereas previous studies have shown that SOS did not cause additional adverse effects in patients following oral intubation, it would still be essential to assess whether SOS causes nasal injury or other complications. Results of our study indicated that the incidence of adverse events between the SOS and FOB groups was comparable. As a visible stylet, the SOS tip can be positioned in close proximity to the side orifice of the tracheal tube to prevent damage to the intranasal and surrounding tissues.

In terms of alternative approaches, indeed previous studies have demonstrated several devices and techniques for overcoming the drawbacks of FOB. Awake blind nasotracheal intubation (BNTI) is an economical alternative for management of difficult intubation. BNTI presented a comparable total success rate and intubation time as FOB in awake nasal intubation.[31,32] However, BNTI is restricted by a low incidence of success on the first attempt.[26] Moreover, during blind intubation, the performer is not able to visualize the airway structures. These drawbacks may result in traumatic or even irreversible consequences, especially in patients with head and neck pathologies. Another well-studied device is the videolaryngoscope. Clinical trials have indicated that it is a safe and effective alternative to FOB for awake nasal intubation in head and neck surgery patients with difficult airway and has a similar success rate compared to FOB with shorter intubation time.[14,33] However, use of the videolaryngoscope is highly limited for nasotracheal intubation in patients with microstomia, severely restricted mouth-opening, or large intraoral masses, which frequently present in head and neck surgery patients. On the other hand, SOS has a visual intubating stylet that provides direct vision during advancement such that its maneuverability is not affected by mouth-opening and intraoral space. Therefore, SOS is considered more widely applicable for awake nasal intubation in the management of difficult airway in patients undergoing head and neck surgery.

There are several limitations to this trial. First, all the included patients underwent elective surgery and patients with upper airway emergencies were not included. Second, our postoperative follow-up did not assess the comfort of patients. Notably, previous studies that compared the efficiency of different intubation devices evaluated the comfort of patients during awake intubation using the visual analog scale.[19,34] In our study, however, sedation was induced using midazolam; thus, the subsequent anterograde amnesia caused by midazolam may affect memory of the intubation procedure. Body resistance or movement can be interpreted as severe discomfort, and in our study no significant differences were observed between the two groups. Third, intubation in our study was performed by experienced providers. Hence, our results demonstrated the differences between the two techniques rather than the differences between operators with different skill levels. Our results may not reflect the outcomes of intubations performed by less experienced anesthetists or novice clinicians. Fourth, it is impossible to blind either the patients or anesthetists to the technique; therefore, this could have introduced potential bias. Last, the present data were collected following procedures conducted in a single institution. Hence, the replicability of the current findings should be assessed in other institutions and environments.

CONCLUSION

The present RCT showed that, although both FOB and SOS provided high success rates of awake nasal intubation, SOS required a shorter intubation time and fewer airway assisted maneuvers when used by experienced performers. The incidence of adverse events in both SOS and FOB groups was comparable. However, there are disadvantage to FOB that SOS does not have, such as maneuverability challenges, difficulty in tube advancement, and protracted training period. Alternatives such as BNTI and videolaryngoscope also have distinct limitations for application in head and neck surgery patients. Therefore, SOS could be a potential alternative to FOB for awake nasal intubation in patients undergoing head and neck surgery with predicted difficult airway.

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