

Original Article

The effects of on hemodynamics, oxygen saturation, peak airway pressure and adverse events during anesthesia for thyroid surgery: tracheal intubation Vs. ProSeal laryngeal mask airway

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Abstract: Objective: To investigate the effect of tracheal intubation and ProSeal laryngeal mask airway (PLMA) on hemodynamics, oxygen saturation, peak airway pressure and adverse events during anesthesia for thyroid surgery. Methods: 65 patients who underwent luminal thyroid surgery under general anesthesia were enrolled as the study subjects, and were divided into control group (30 patients, tracheal intubation) and experimental group (35 patients, PLMA) using random number table. The time to establishment of artificial airway and success rate, hemodynamics, oxygen saturation, peak airway pressure and adverse effects were observed in the two groups. Results: The SBP, DBP, and HR levels of patients in the experimental group were significantly lower than those of control group ($P < 0.05$), and there were no significant changes in SBP, DBP, and HR levels during the insertion and removal of the laryngeal mask, and the patients were hemodynamically stable. SpO_2 and Ppeak values remained stable at 5 min, 30 min, and 60 min after the start and the end of surgery in both groups, and showed no significant difference between the two groups ($P > 0.05$). A surgical airway was quickly established in both groups, and the time to airway establishment was shorter in the experimental group than in the control group. The incidence of adverse reactions during extubation was lower in the experimental group than in the control group, and the incidence of hoarseness, choking and cough differed significantly between the two groups ($P < 0.05$), and the adverse reactions in both groups were relieved or disappeared 24 h after the operation. Conclusion: With LMPA, patients are more hemodynamically stable during insertion and removal of the mask, have a lower incidence of adverse events, and experience less throat irritation, with safety.

Keywords: Tracheal intubation, Proseal laryngeal mask, thyroid, hemodynamics, adverse effects

Introduction

Thyroid disorders include hyperthyroidism, hypothyroidism, thyroid inflammation, thyroid nodules and thyroid cancer. The prevalence of thyroid disease has increased significantly in recent years, with more than 200 million people worldwide suffering from thyroid disease, affecting more women than men [1]. The global incidence rate of thyroid cancer was highest among all cancers, with a 211% increase in the incidence of thyroid cancer in the United States over the past 30 years, and the incidence of thyroid cancer is among the highest in China's tumor incidence surveys [2, 3].

Traditional thyroid surgery is traumatic. With incision in the neck, patients are prone to post-operative complications such as local tissue swelling, bringing serious psychological burden to patients, especially female patients. With the continuous development of laparoscopic technology, Gagner et al. first reported the laparoscopic parathyroidectomy in 1996, and Henry et al. proposed a lateral endoscopic approach in 1999, which has become a main treatment option for thyroidectomy [4, 5]. Various indications for laparoscopic thyroidectomy exist. Cuff inflation was performed to create operation space, so that parathyroid glands, blood vessels, etc. were clearly exposed, reducing the

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risk of intraoperative injury and complications. It causes small size of trauma surface with practically invisible scar.

Endotracheal intubation (ETT) used to be the gold standard for airway management, but the process of intubation and extubation is prone to irritation of the pharynx and voice valves, leading to fluctuations in blood pressure and heart rate [6]. To overcome the drawbacks of ETT, the laryngeal mask was developed. The laryngeal mask has the advantages of low-level stress and low stimulation to the larynx, and has been widely used as a novel artificial airway, especially in the treatment of patients with difficult intubation [7, 8]. Proseal laryngeal mask is the third generation type, which is easy to use, less irritating, and prevents reflux aspiration. It is not easy to dislocate during the operation [9, 10].

This study aimed to apply the traditional tracheal intubation and Proseal laryngeal mask in thyroid patients, and compare the effects of different anesthesia methods on patients' hemodynamics, blood oxygen saturation, peak airway pressure and adverse reactions, and through comparative analysis, discuss the safety and feasibility of Proseal laryngeal mask over traditional tracheal intubation.

Materials and methods

Baseline data

Sixty-five patients admitted to our hospital from January 2019 to April 2020 were enrolled. Among them, there were 22 males and 43 females, aged 20-50 years.

Inclusion criteria: patients who would undergo endoscopic thyroid surgery under general anesthesia; and those with ASA of Class I-II [11] were included.

Exclusion criteria: patients with cervical line angle $< 15^\circ$, maximal mouth opening < 2 cm, severe cardiopulmonary impairment, history of gastroesophageal reflux, tracheal stenosis and difficulty intubation.

The 65 subjects were divided into 30 cases in the control group and 35 cases in the experimental group using the random number table method. The differences between the two

groups in baseline data such as gender, age, weight, operation time and time to resuscitation were not significant ($P > 0.05$), which were comparable.

A personal file was established on the 65 patients enrolled, and information such as name, gender, age, contact number, and home address were registered, and an informed consent was signed for voluntary participation in this study. This study was reviewed and approved by the ethics committee of our hospital.

Intervention methods

Anesthesia was performed by the same anesthesiologist in both groups to prevent experimental errors caused by the differences in skill levels of the anesthesiologists. Except for airway management between the two groups, the anesthetics and procedures used were all unified.

Participants fasted for 12 h and abstained from water for 4 h before surgery. 0.5 mg of atropine was injected intramuscularly before anesthesia (China Resources Shuanghe Pharmaceutical Co., Ltd., Lot No.:H11020766). After entering the operating room, the patient's heart rate (HR), electrocardiogram (ECG), blood pressure (BP), oxygen saturation (SpO_2) and end-respiratory carbon dioxide partial pressure ($P_{ET}CO_2$) were monitored using a multifunctional monitor (Mindray, Shenzhen), and the patient's BIS was visualized using an anesthesia monitor YY-106 (Zhejiang Yiyang Medical Technology Co., Ltd.). Anesthesia was induced by intravenous injection of 0.04 mg/kg midazolam (Jiangsu Enhua Pharmaceutical Co., Ltd., Lot: SFDA H20031037), 3 μ g/kg fentanyl (Yichang Renfu Pharmaceutical Co., Ltd., Lot: SFDA H42022076), and 0.1 mg/kg vecuronium bromide (Hainan Star Pharmaceutical Co., Ltd., Lot: SFDA H20065177).

After successful induction of anesthesia, the control patients were given tracheal intubation after exposure of the glottis with a laryngoscope, and the tube was fixed after intra-esophageal insufflation.

After successful induction of anesthesia, the experimental group received Proseal laryngeal mask. When the mask was placed, and air was

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injected until a sac pressure of < 60 cmH₂O. After completion of injection of air, the mask was fixed. The Proseal mask (Shanghai Shengshou Medical Equipment Co., Ltd.) was selected according to the patient's weight, with the weight < 50 kg (size 3) and the weight > 50 kg (size 4).

Outcome measurement

Airway establishment time and success rate

The time taken from placement of the endotracheal tube/Proseal laryngeal mask to effective ventilation and the success rate of mask placement were recorded.

Hemodynamic parameters

Hemodynamics can be used to closely monitor critically ill patients, thus health care professionals can administer cardiovascular drugs based on changes in vital parameters. The main hemodynamic indices include AP, HR, CVP, RAP, RVP, and PAP [12, 13]. Blood pressure (SBP, DBP) and heart rate (HR) values were recorded in both groups of patients before induction of anesthesia, 1 and 3 min after catheter/Proseal mask insertion, and 1 and 3 min after removal of catheter/Proseal mask.

Oxygen saturation indices

SpO₂ reflects the concentration of oxygen in the blood and is an important index in the respiratory cycle. The oxygen saturation of normal human arterial blood and venous blood is 98% and 75%, respectively. A decrease in oxygen saturation often indicates obstructed airway [14]. SpO₂ values were recorded in both groups after catheter/Proseal laryngeal mask placement and at 5 min, 30 min, and 60 min after the start and at the end of the procedure.

Peak airway pressure

Mechanically ventilated patients should be monitored with dedicated respiratory monitors, with Ppeak monitoring being the most commonly used method, and over high airway pressure can affect the ratio of blood flow and ventilation. During the procedure, the intra-catheter balloon pressure should be adjusted according to the change in peak airway pressure, otherwise effective ventilation will not be achieved

[15]. Ppeak values were recorded at the same time points mentioned above.

Adverse events

Adverse reactions such as reflux misaspiration, signs of bleeding on the catheter/mask, hoarseness, choking, and pharyngeal pain after the removal of the tracheal tube/Proseal laryngeal mask were recorded [16]. The adverse reactions were observed 24 h after surgery.

Statistical methods

Data analysis was performed using SPSS 17.0 software. GraphPad Prism 8 was used to create the statistical charts. The measurement data were expressed as mean \pm standard deviation ($\bar{x} \pm sd$), and differences between groups were compared using the t-test. $P < 0.05$ indicated that the difference was significant.

Results

Comparison of differences in baseline data

The control group included 9 males and 21 females, with an average age of 39.87 ± 5.87 years, while the experimental group included 13 males and 22 females, with an average age of 40.05 ± 6.32 years. There was no significant difference in terms of general clinical indicators such as sex, age, weight, surgery and time of awakening between the two groups, which were comparable ($P > 0.05$) (**Table 1**).

Comparison of airway establishment time and success rate

Time to successful insertion of Proseal mask in the experimental group was significantly shorter than that in the control group, with significant difference ($P < 0.05$). The success rate of placement was 100% in both groups, but the success rate of Proseal laryngeal mask placement with one try in the experimental group was lower than the 94.28% of the control group (**Table 2**).

Analysis of changes in hemodynamic parameters

Before the induction of anesthesia, the levels of SBP, DBP, and HR were 118.75 ± 20.13 , 69.74 ± 13.16 , and 76.92 ± 16.75 in the experi-

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Table 1. Comparison of baseline data between the two groups ($\bar{x} \pm sd$)/[n (%)]

Baseline data		Control group (n=30)	Experimental group (n=35)	t/X ²	P
Gender	Male	9	13	-3.000	0.205
	Female	21	22		
Average age		39.87±5.87	40.05±6.32	-0.095	0.874
Average weight (kg)		50.62±8.74	51.37±8.40	-0.317	0.762
Operating time (min)		56.75±5.32	54.38±3.42	-0.095	0.916
Time to awakening time (min)		5.27±2.96	4.88±2.34	-0.415	0.673

Table 2. Comparison of the time and success rate of artificial airway establishment after the intervention in the two groups of patients

Grouping	Establishment time (s)	One-time success (cases, %)	Overall success (cases, %)
Control group	31.65±4.17	30 (100)	30 (100)
Experimental group	8.63±1.52*	33 (94.28)	35 (100)
t/X ²	0.736	0.613	
P	0.003	0.027	

*Represents a significant difference in the establishment time between the experimental group and the control group.

mental group and 116.52±22.36, 67.53±13.20, and 75.18±12.36 in the control group, respectively, with no significant difference between the two groups ($P > 0.05$). After the intervention, the SBP, DBP, and HR levels of the experimental group were significantly lower than those of the control group ($P < 0.05$), which were increased in both groups when the catheter/Proseal laryngeal mask was removed (**Figure 1**).

Analysis of changes in blood oxygen saturation

After placement of catheter/Proseal laryngeal mask, SpO₂ was stable in both groups at 5, 30, and 60 min after the start of the procedure, with no significant difference at the same time point between the groups ($P > 0.05$), demonstrating that effective ventilation can be achieved quickly in both groups during the surgery (**Figure 2**).

Analysis of changes in peak airway pressure

Ppeak values increased in both groups at 5, 30, and 60 min after the start of the procedure, but the difference between the groups at the same time point was not significant ($P > 0.05$). There was 1 case of air leakage in the experimental group. After adjusting the position of the Proseal laryngeal mask, the air leakage dis-

appeared without changing ventilation tools (**Figure 3**).

Comparison of adverse reactions

The incidence of adverse events after removal of catheter/Proseal laryngeal mask in the experimental group was lower than that in the control group. There was a significant difference in the incidence of hoarseness and choking

between the two groups ($P < 0.05$) (**Figure 4**). During the 24-h postoperative follow-up, a few patients still had symptoms of hoarseness and pharyngeal pain, but the discomfort and all other adverse reactions were relieved (**Figure 5**).

Discussion

For procedures that are difficult to perform with local anesthesia, general anesthesia is required, and tracheal intubation is the most common option. Although tracheal intubation was suitable for multiple types of procedures, it is prone to greater irritation of the patient's pharynx and can cause large fluctuations in hemodynamic parameters during intubation and extubation, which can interfere with the procedure. In addition, tracheal intubation also predisposes patients to complications such as glottal injury and infection, soft tissue damage, hoarseness, and cardiac arrhythmias.

Laryngeal mask airway (LMA) happens to compensate for the limitations that exist in tracheal intubation. LMA was first used in clinical practice by A. Brain in 1981 and was initially designed to replace conventional masks to achieve general anesthesia in a short period of time [17]. The LMA is designed according to the structure of the human pharynx without expos-

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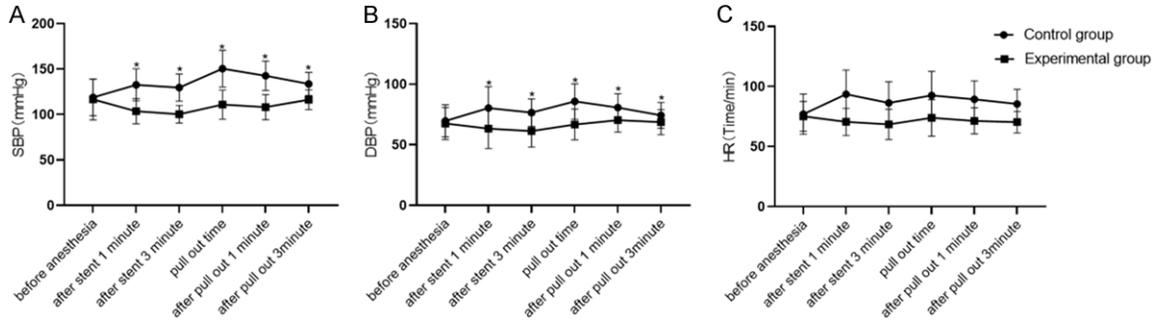


Figure 1. Changes in hemodynamic parameters after intervention using different modalities. A comparative analysis revealed that before induction of anesthesia, the differences in SBP, DBP, and HR levels between the two groups were not significant, and when the catheter/Proseal laryngeal mask was removed, SBP, DBP, and HR levels were increased in both groups. * $P < 0.05$.

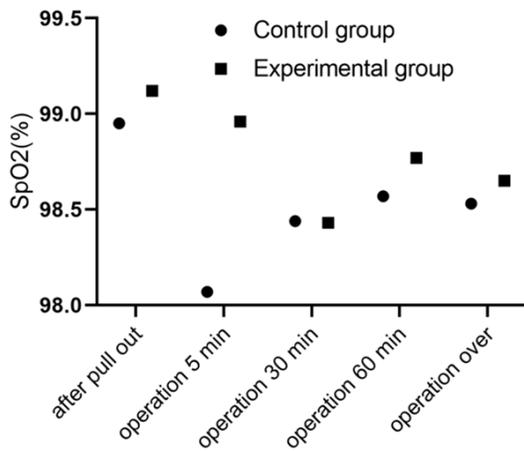


Figure 2. Analysis of changes in oxygen saturation. SpO_2 was stable in both groups at 5 min, 30 min and 60 min after the start of surgery ($P > 0.05$).

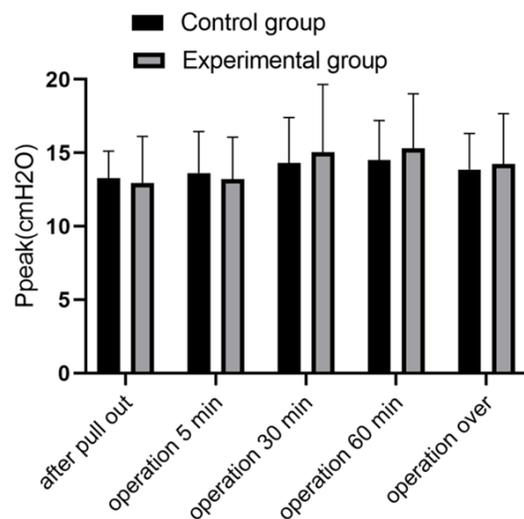


Figure 3. Analysis of the change of airway peak pressure after intervention using different ways. Ppeak value increased in both groups at 5 min, 30 min, and 60 min after the start of surgery ($P > 0.05$).

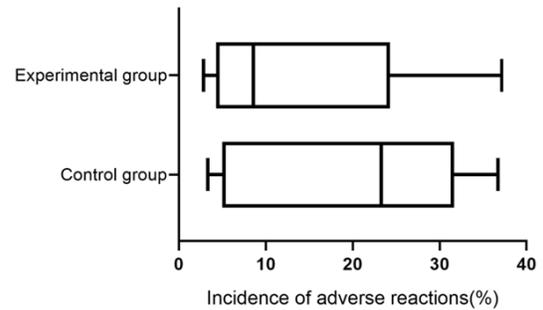


Figure 4. Postoperative adverse events after intervention using different modalities. The incidence rate of adverse events in the experimental group was lower than that in the control group ($P < 0.05$).

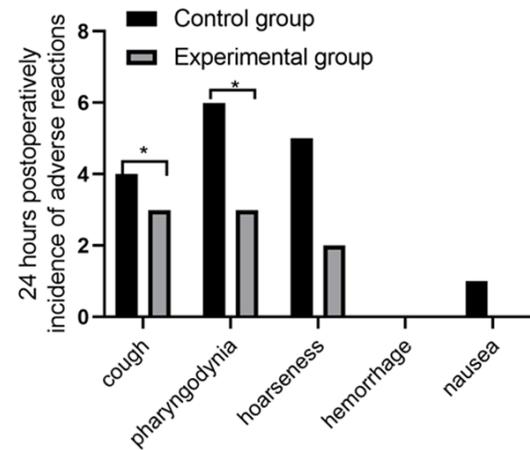


Figure 5. Analysis of adverse reactions 24 h after surgery using different ways of intervention. The occurrence of adverse reactions was reduced in both groups 24 h after surgery, and the number of cases of each adverse reaction in the experimental group was lower than that in the control group ($P < 0.05$).

ing glottis, which reduces irritation to the glottis during insertion and removal. LMA is widely

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used in surgical procedures due to its advantages such as easy operation, high reliability, and low irritation to the pharynx [18-20]. LMA has gone through the process of CLMA, ILMA to PLMA, and the Proseal laryngeal mask is the third generation of PLMA mask, which is made of silicone rubber to better fit the patient's pharynx and remain airtight even when the position is changed. The Proseal laryngeal mask has a double capsule and suction tube structure that prevents the occurrence of counter-current mistake inhalation and reduces complications [21].

Studies have shown that LMA provides better control of patient hemodynamics, reduces the risk of cardiovascular complications, and improves patient safety during the perioperative period [22, 23]. In thyroid surgery, by monitoring the patient's SpO₂ and Ppeak, it is possible to monitor whether the laryngeal mask is displaced or leaking air, and if the monitoring values are abnormal, the cause and the ventilation device were replaced with a new one if necessary [9, 24].

In this study, patients undergoing laparoscopic thyroid surgery under general anesthesia were divided into groups, and tracheal intubation and Proseal laryngeal mask were used for anesthesia treatment. The results showed that since Proseal laryngeal mask does not enter the glottis and trachea during insertion, the levels of SBP, DBP, and HR of the experimental group of patients did not change significantly when the laryngeal mask was inserted and removed, and the hemodynamics of the patients were stable, which had little effect on the circulation of the patients. After the placement of catheter/Proseal laryngeal mask, there were no significant differences in SpO₂ and Ppeak at 5 min, 30 min, and 60 min after the start of surgery in the two groups, proving that both tracheal intubation and Proseal laryngeal mask can quickly establish an effective airway, and the comparison of establishment time showed that the time required to establish the passage in the Proseal laryngeal mask experimental group was shorter than that in the control group, which was more conducive to the surgery.

In summary, Proseal laryngeal mask can stabilize the patient's hemodynamics during thyroid surgery, and the irritation to the throat of the

patient is less than that of ordinary tracheal intubation. The incidence of adverse reactions in patients using Proseal laryngeal mask is low, worthy of clinical application. The innovation of this study is applying the Proseal laryngeal mask during anesthesia in thyroid surgery while exploring its effects on hemodynamics, SpO₂ values and Ppeak values, and the adverse reactions of patients after the removal of the Proseal laryngeal mask. Efforts were made to provide more effective and less harmful airway management for patients undergoing thyroid surgery to ensure perioperative safety.

The shortcomings of this study include the following: (1) Small sample size, making the results less generalizable. (2) The number of indicators is limited. In order to address the above shortcomings, the next step is to carry out a multi-regional study with a large sample size and more comprehensive monitoring indicators, in order to provide a more detailed theoretical basis for the better application of Proseal masks in anesthesia for thyroid surgery.

Disclosure of conflict of interest

None.

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