อาการไม่สบายในคอหลังจากใส่ท่อหายใจระหว่าง LMA-ProSeal™ กับ Profile Soft-Seal Cuff™ ในผู้ป่วยนอกที่มารับการส่องกล้องทางนรีเวช

นาง เกศชาดา เอื้อไพโรจน์กิจ

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POSTOPERATIVE THROAT DISCOMFORT AFTER USING LMA-PROSEAL™ VERSUS PROFILE SOFT-SEAL CUFF™ FOR ANESTHESIA IN AMBULATORY GYNECOLOGIC LAPAROSCOPY

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A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science in Health Development
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Thesis title	Postoperative throat discomfort after using LMA-ProSeal™ versus Profile Soft-Seal Cuff™ for anesthesia in ambulatory gynecologic laparoscopy
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เกศชาดา เอื้อไพโรจน์กิจ: อาการไม่สบายในคอหลังการใส่ท่อหายใจระหว่าง LMA-ProSeal™ กับ Profile Soft-Seal Cuff™ ในผู้ป่วยที่มารับการส่องกล้องทางนรีเวช. ((POSTOPERATIVE THROAT DISCOMFORT AFTER USING LMA-PROSEAL™ VERSUS PROFILE SOFT-SEAL CUFF™ FOR GENERAL ANESTHESIA IN AMBULATORY GYNECOLOGIC LAPAROSCOPY.) อ. ที่ปรึกษา : รศ.นพ.สมรัตน์ จารุลักษณานันท์, อ.ที่ปรึกษาร่วม : รศ.นพ. เทวารักษ์ วีระวัฒกานนท์, 54หน้า. ISBN 974-17-6950-4

วัตถุประสงค์: เพื่อเปรียบเทียบความรุนแรงของอาการไม่สบายในลำคอ ได้แก่ อาการเจ็บคอ, กลืนลำบาก และเสียงแหบ ระหว่างการใส่ท่อหายใจแบบ LMA-ProSeal™ (PLMA) กับท่อหายใจแบบ Profile Soft-Seal Cuff™ endotracheal tube (PSSC) ในระยะแรก (2 ชม.) และระยะหลัง (24 ชม.) หลังผ่าตัดส่องกล้องทางนรีเวชแบบผู้ป่วยนอก

รูปแบบการศึกษา: การศึกษาเชิงทดลองทางคลินิกแบบปกปิดสองฝ่ายโดยการสุ่มตัวอย่าง

สถานที่ทำการวิจัย: โรงพยาบาลจุฬาลงกรณ์เฉลิมพระเกียรติ ซึ่งเป็นโรงพยาบาลระดับตติยภูมิ

วิธีการศึกษา: ผู้ป่วย 138 รายที่มารับการส่องกล้องทางนรีเวชแบบผู้ป่วยนอก จะได้รับการจัดเป็น 2 กลุ่มโดยวิธีสุ่มคือ กลุ่มหนึ่งได้รับการใส่ท่อหายใจด้วย PSSC และอีกกลุ่มหนึ่งด้วย PLMA โดยทั้ง2กลุ่มได้รับยาสลบตามวิธีมาตรฐาน ประเมินอาการเจ็บคอ, กลืนลำบาก, และเสียงแหบ และอาการคลื่นไส้หรืออาเจียน ที่ 2 และ 24 ชั่วโมง, ความพึงพอใจที่ 5 ระดับ ต่อวิธีที่ได้รับการใส่ท่อหายใจเมื่อครบ 24 ชั่วโมง

ผลการศึกษา: ผู้ป่วยมีอาการเจ็บคอและเสียงแหบ ณ เวลา 2 ชั่วโมงในกลุ่ม PLMA น้อยกว่า PSSC (P = 0.016 และ P = 0.003 ตามลำดับ) แต่ไม่พบความแตกต่าง ณ เวลา 24 ชั่วโมง รวมทั้งความแตกต่างของอาการกลืนลำบาก คลื่นไส้ อาเจียน และความพึงพอใจระหว่างกลุ่ม

สรุป: PLMA ทำให้เกิดอาการเจ็บคอและเสียงแหบในระยะแรกน้อยกว่า PSSC PLMA จึงเป็นอีกทางเลือกหนึ่งของท่อหายใจสำหรับการดมยาสลบในการส่องกล้องทางหน้าท้องในผู้ป่วยนอกทางนรีเวช

ภาควิชา การพัฒนาสุขภาพ ลายมือชื่อนิสิต .....

สาขาวิชา การพัฒนาสุขภาพ ลายมือชื่ออาจารย์ที่ปรึกษา .....

ปีการศึกษา 2547 ลายมือชื่ออาจารย์ที่ปรึกษาร่วม.....

4675001730 : MAJOR HEALTH DEVELOPMENT

KEY WORD:SORE THROAT/ LMA PROSEAL™/ LAPAROSCOPY/ PROFILE SOFT-SEAL CUFF™

KETCHADA UERPAIROJKIT : POSTOPERATIVE THROAT DISCOMFORT AFTER USING LMA-PROSEAL™ VERSUS PROFILE SOFT-SEAL CUFF™ FOR GENERAL ANESTHESIA IN AMBULATORY GYNECOLOGIC LAPAROSCOPY. THESIS ADVISOR : ASSOC. PROF. SOMRAT CHARULUXANANAN, THESIS COADVISOR : ASSOC. PROF. THEWARUG WERAWATGANON, 54 pages. ISBN 974-17-6950-4

Objective: To compare the severity of throat discomfort in terms of sore throat, dysphagia and dysphonia caused by LMA-ProSeal™ (PLMA) and Profile Soft-Seal Cuff™ (PSSC) in early (2 hour) and late (24 hour) postoperative period after ambulatory gynecologic laparoscopy.

Design: Randomized double-blind controlled trial

Setting : King Chulalongkorn Memorial Hospital which is the tertiary care center.

Research Methodology: One hundred and thirty-eight patients undergoing ambulatory gynecologic laparoscopy were randomly allocated into 2 groups. The patients in one group were intubated with Profile-Soft-Seal Cuff™ (PSSC), while the other with ProSeal LMA™ (PLMA). Four-leveled score of sore throat, dysphagia, dysphonia, nausea or vomiting symptoms at 2 and 24 hour and 5-leveled satisfaction score to both techniques at 24 hour postoperatively were evaluated.

Results : The patients in PLMA group have less severe symptoms of sore throat ($p = 0.016$) and dysphonia($P = 0.003$) than those in PSSC group only at 2 but not at 24 hour postoperatively. No difference was detected for dysphagia, nausea, vomiting and satisfaction scores.

Conclusion : PLMA caused less sore throat and dysphonia in early postoperative period than PSSC did. PLMA can be used as an alternative airway device for anesthesia in ambulatory gynecologic laparoscopy.

Department Health Development Student's signature……

Field of study Health Development Advisor's signature……

Academic year 2004 Co-advisor's signature……..

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CHAPTER 1

INTRODUCTION

1.1 Rationale and background

Healthcare quality can be improved by eliciting patient preference and customizing cares to safely meet the needs of the patient. Throat discomfort is one of the most undesirable outcomes after ambulatory anesthesia (1). Many patients complain about uncomfortable feelings of the pharynx and larynx after endotracheal intubation, which include sore throat, dysphagia, and dysphonia. Moreover, these throat irritations may stimulate the cranial nerve of laryngopharynx and induce the higher incidence of postoperative nausea and vomiting (PONV) (2). These undesirable symptoms may also have strong influence on patient's satisfaction, daily activities, and quality of life after discharge.

Airway management during anesthesia has the strongest influence on the incidence of throat discomfort after anesthesia. Higgins, Chung, and Mezei studied 17,638 ambulatory surgical patients prospectively and found that 45.4% of patients suffered from sore throat after endotracheal intubation (ETT), as compared to 17.5% after the use of a laryngeal mask airway (LMA) (3). Apart from the symptoms of sore throat, the incidence of dysphonia is also higher among ETT patients. However, LMA insertion produces more dysphagia than ETT (4).

For the procedure of gynecologic laparoscopy, ventilation control during intraperitoneal carbon dioxide insufflation is needed. The airway device must have high efficacy for positive pressure ventilation and airway protection from gastric aspiration. The original LMA may not be an effective alternative to ETT for its excess of gas leak and the unreliable protective effect of gastric aspiration. Recently, the LMA- ProSeal™ (PLMA: the Laryngeal-Mask Company, Henley-on-Thames, UK, Appendix1) was designed to permit higher airway pressure than the LMA-Classic™ (CLMA: the Laryngeal-Mask Company, Henley-on-Thames, UK) with less leak of anesthetic gases (5). PLMA produces better seal in anesthetized and paralyzed patients than CLMA.

Moreover, PLMA facilitates gastric tube or suction tube placement for decompression and suction of the regurgitated gastric fluid. Based on these characteristics, many studies confirmed the efficacy of PLMA as an adequate airway device for respiratory support and airway seal in gynecologic laparoscopy (6) and laparoscopic cholecystectomy (7).

In gynecologic laparoscopy, pneumoperitoneum induces higher airway pressure. Therefore, higher inflated cuff pressure is needed to avoid gas leak around the laryngopharynx into the stomach. Many reports found an association between high cuff pressure of endotracheal tube and sore throat (8,9). The increase in intra-cuff pressure during anesthesia depends on nitrous oxide (N_2O) diffusion and cuff compliance. The Profile Soft-Seal Cuff ™ (PSSC: Sims Portex, Kent, UK, Appendix1) is a new endotracheal tube which belongs a cuff composed of a material with N_2O gas-barrier properties and higher compliance (10). Karasawa, et al. reported the lower incidence of sore throat when it was compared with the standard use of an endotracheal tube especially for long duration anesthesia (11). Even though the lower incidence of sore throat has been reported in LMA but cuff pressure will also increase by N_2O diffusion especially in longer duration of anesthesia (12, 13, 14) and this will compromise mucosal capillary pressure in the posterior pharynx or larynx and may lead to throat discomfort. However, there still has been no study which compares the differences of these throat symptoms and the incidence of nausea or vomiting after PLMA and PSSC. The aim of this study is to compare the following undesirable feelings of the pharynx and the larynx; i.e., sore throat, dysphagia, and dysphonia in an ambulatory anesthesia for patients undergoing gynecologic laparoscopy for which high airway pressure is needed.

1.2. Literature review

Literature search strategy

The literature search strategy used to locate the information in this review is the PubMed reference database and additionally by going through the reference list of other articles and institutional database. The search terms used were “sore throat OR dysphagia OR dysphonia AND (endotracheal intubation OR LMA)”. The most recent time that the articles were retrieved from PubMed was on March 18, 2005, and there were 619

articles. When the search term were added with “And postoperative*”, the number was reduced to 210 articles, which were 88 RCTs (83 in English).

There were 49 articles: 15 RCT were retrieved by the search terms “ProSeal LMA”, and 14 articles: 5 RCT by “Profile Soft-Seal”. When these terms were combined with “AND (sore throat OR dysphagia OR dysphonia)”, 7 articles were retrieved for PLMA and 2 for PSSC. So far, there is no meta-analysis on throat discomfort in both airway devices.

Postoperative throat discomfort

Symptoms of postoperative throat discomfort such as sore throat, hoarseness and dysphagia are common. Many patients complain about discomfort in the pharynx and the larynx after anesthesia, which might have a strong influence on their satisfaction, daily activities and quality of life after discharge. These complaints should be much more emphasized on an ambulatory patient who needs to gain normal functional capability such as water and food intake after a long period of fasting, to avoid postoperative nausea and vomiting, and to achieve their usual level of performance.

Airway management during anesthesia has the strongest influence on the incidence of throat discomfort after anesthesia (3). During anesthesia, compression pressure applied on the laryngotracheal mucosa by the airway devices produce vascular congestion, pressure necrosis and airway trauma. The highest incidence of sore throat and other airway-related symptoms tends to occur in patients who have undergone tracheal intubations (3, 15). There is a wide variation in the statistics of the incidents, which is presumably due to different skills and techniques among anesthesiologists and to differences between researchers and patients in the definition of sore throat. It is well recognized that the method of questioning is an important determinant of the incidence of sore throat (16). Recently, some studies specified the symptoms of throat discomfort separately. Sore throat is a constant pain, independence of swallowing. Dysphagia is discomfort with swallowing provoked by drinking. Dysphonia is the changes of voice, difficult speaking, and pain on speaking (17, 18). These undesired symptoms may occur differently, depending on the different airway techniques.

Sore throat following tracheal Intubation

Many cuff designs have been continuously improved to diminish the incidence of sore throat. High-volume, low-pressure cuffed endotracheal tube has commonly been used to avoid tracheal mucosal ischemia. Unfortunately, the greater area of cuff-tracheal contact produces more sore throat, especially when the intra-cuff pressure is too high.

Many reports confirm about the correlation of the incidence of sore throat or tracheal morbidity and intra-cuff pressure (8, 9). Diffusion of nitrous oxide into the cuff of the airway device will increase cuff pressure increase tracheal mucosal erosion time-dependently. Recently, another new endotracheal tube cuff, the Profile Soft-Seal Cuff ™ (PSSC), made of a material impermeable to N_2O, was developed and the efficacy has been reported (10). Karasawa , et al. reported the lower increase of intra-cuff pressure and less postoperative sore throat during N_2O anesthesia when PSSC was compared with standard endotracheal tubes (11). Careful control of intra-cuff pressure may be beneficial even for short term intubation.

Sore throat and the laryngeal mask airway

Nowadays, use of LMA during surgery has exploded. Since its commercial introduction in 1988, there are now over 2,000 publications pertaining to the LMA. In 1995, Brimacombe summarized the advantages and disadvantages of the LMA compared with tracheal intubation (19). The advantages included haemodynamic stability at induction compared with intubation, and during emergence compared with extubation; minimal increase in intraocular pressure after insertion; reduce anesthetic requirements for airway tolerance; lower frequency of coughing during emergence, improve oxygen saturation during emergence; and a lower incidence of sore throat in adults. Additionally, LMA is an alternative airway technique in the case of difficult intubation.

In the physiological aspect, LMA impairs mucociliary clearance, as measured by mucus transport velocity, less than a tracheal tube does (20). This may have implications for reducing the risk of retention of secretions, atelectasis and pulmonary infection. Many studies have been published in which direct comparisons were made between the LMA and the tracheal tube with reference to intra-operative use and postoperative throat

complaints. The so-called 'sore throat' was more clearly defined into 3 more precise symptoms. These are sore throat (continuous throat pain), dysphonia (voice changes), dysphagia and pharyngeal dryness (15, 17, 18).

About postoperative throat discomfort, since the LMA cuff compresses on the posterior pharynx and the entry of esophagus, dysphagia is commonly found. Dysphonia is more common after endotracheal intubation because of the compression to the entry of the trachea (4, 21). About the cuff of LMA, it is made of silicone which is not nitrous oxide gas barrier. Postoperative sore throat was found more in the patients whose cuff pressure was not carefully limited.

The incidence of sore throat is reportedly related to the size and inflation pressure of the cuff volume of airway devices (8,9,12,13,14) For the LMA, size 4 for female provide a better seal than a smaller one (size 3) without producing a higher pressure on the pharynx (22,23). According to the design of LMA, the incidence of sore throat is not different when PLMA was compared with the LMA-Classic™, unless it is more difficult to insert (24).

The LMA- ProSeal™ vs. endotracheal intubation for laparoscopy

For a patient undergoing gynecologic laparoscopy, being in Trendelenberg position with intra-abdominal insufflation is an important factor in increasing the risk of aspiration and inadequate ventilation. Formerly, cuffed endotracheal tube was accepted because of its property of aspiration prevention. However, this is not completely reliable, as the redundant cuff would wrinkle and cause deep mucosal grooves which permit regurgitation of supraglottic content (15).

LMA-ProSeal™ (PLMA) is an innovative device from LMA-Classic™ (CLMA). An article describing one of these prototypes was published in 1995 (25). To form a better seal, it incorporates a larger, conical-shaped distal cuff to fill the hypopharynx more completely and the larger, wedge-shaped proximal cuff to fill the proximal laryngopharynx more completely. It also composes of a drainage tube, located behind the airway tube and cuff which acts as a conduit for gastric decompression via suction or orogastric tube. Seal pressures are much higher than those in CLMA ($\geq$ 50 cmH_2O), and it provides functional isolation on the respiratory tract from the gastrointestinal tract (26).

These properties of better seal, better airway protection and access to the gastrointestinal tract make PLMA become an alternative airway device to CLMA or endotracheal tube in patients undergoing laparoscopy (6, 7).

Brimacombe and Keller studied regurgitation pressure for various cuff volume of LMA and found that cuff volume of 10 ml or more has the protective effect from pulmonary aspiration and can increase regurgitation volume reaching 1000-1500 ml (26, 27).Therefore, by the design of PLMA, cuff pressure $\geq$ 60 cmH2O should be enough protection from pulmonary aspiration (28). However, there were two case reports of regurgitation in general anesthesia with PLMA, one had protective effect of PLMA (29), but the other did not get complete protection (30).

Besides its suffering symptoms, sore throat may have a correlation with PONV. Pressure at the tube-mucosal interface may sustain evoked parasympathetic impulses through the vagus, recurrent laryngeal, and glossopharyngeal nerves to the vomiting center, thus initiating vomiting responses (2). Therefore, sore throat after the airway devices will aggravate PONV, which is a very common adverse outcome in the laparoscopic patients.

Up to present, a number of economic studies have been performed. The use rate of LMA > 25 times will be more cost-effective than endotracheal tube (31). The company guarantees the use of 40 times for PLMA.

However, up to present, there is no study that compares throat discomfort and PONV produced by PSSC and PLMA in the patients undergoing gynecologic laparoscopy.

CHAPTER 2

RESEARCH METHODOLOGY

2.1 Research Questions

2.1.1 Primary research question

- Is the severity of 2-hr postoperative sore throat after LMA ProSeal™(PLMA) different from after Profile Soft-Seal Cuff™ endotracheal tube (PSSC) in ambulatory gynecologic laparoscopy ?

2.1.2 Secondary research questions

- Does the patient with PLMA have different 24-hr postoperative sore throat, and 2 and 24-hr postoperative dysphagia, and dysphonia after PLMA and PSSC?
- Is the incidence of nausea and vomiting related to the severity of sore throat?
- Is patient's satisfaction to the airway technique in PLMA different from that in PSSC groups?
- Is the cost-minimization of PLMA comparable to PSSC?

2.2 Objectives

1. To compare the severity of sore throat between PLMA and PSSC groups at 2 periods: 2 and 24 hours after extubation.
2. To compare the incidence of postoperative dysphagia, dysphonia, nausea and vomiting and patient's satisfaction to the airway technique between PLMA and PSSC groups.
3. To find the difference in severity of sore throat between the patients with and without nausea or vomiting.
4. To compare the efficacy of lung ventilation between PLMA and PSSC.
5. To compare the cost-minimization of PLMA and PSSC.

2.3 Hypothesis

2.3.1 Research hypothesis

There is difference in severity of sore throat between PLMA and PSSC in patients undergoing gynecologic laparoscopy at 2 and 24 hours postoperatively.

2.3.2 Statistical hypothesis

Null hypothesis

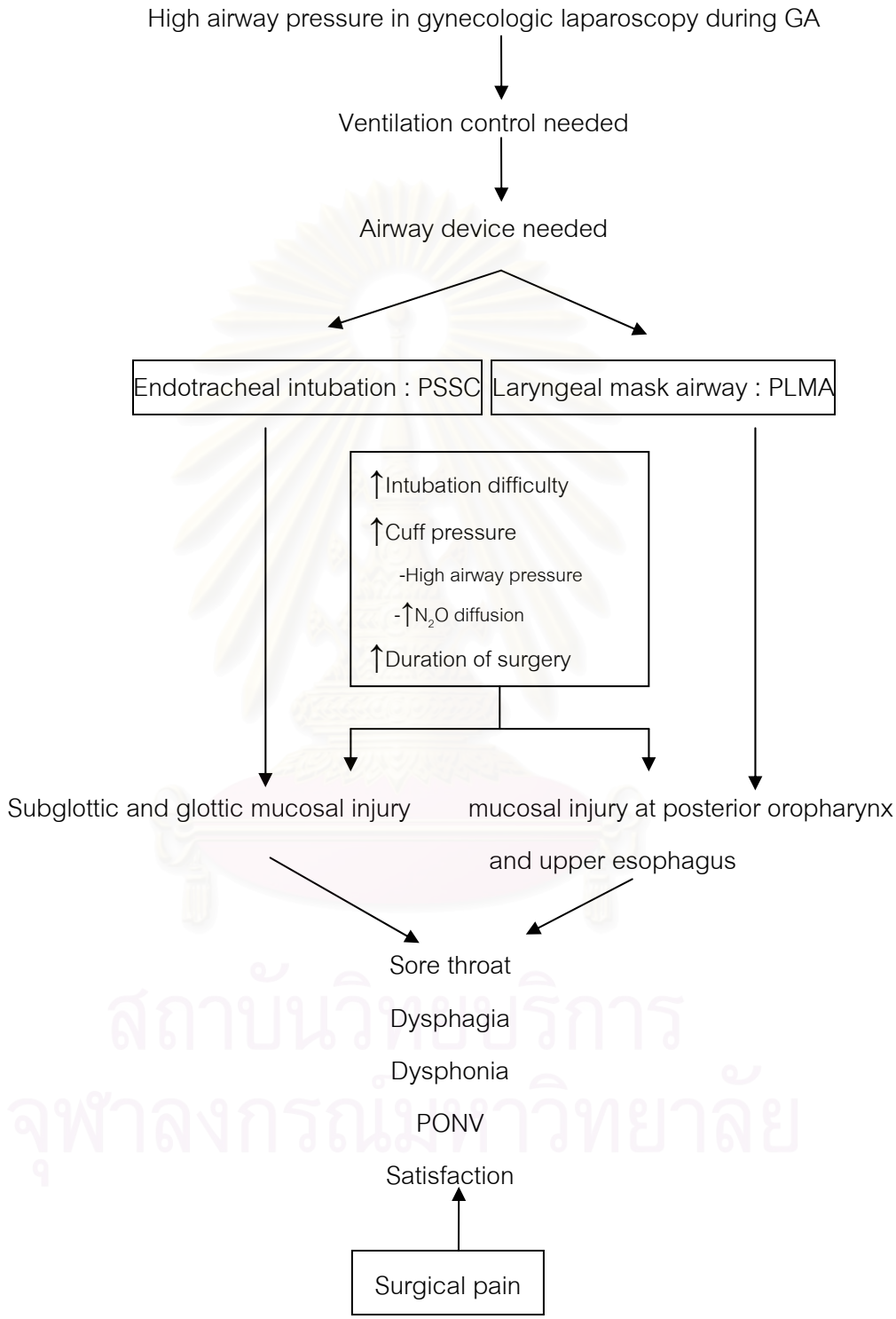
There is no association of the ordering of severity of sore throat after PLMA and PSSC groups in the patients undergoing gynecologic laparoscopy.

Alternative hypothesis

There is an association of the ordering of severity of sore throat after PLMA and PSSC groups in the patients undergoing gynecologic laparoscopy.

2.4 Conceptual framework

Figure 1 Proposed conceptual framework



2.5 Operational definition (17, 18)

- Sore throat is defined as constant pain, independent of swallowing.

- Dysphagia is defined as discomfort with swallowing provoked by drinking.
- Dysphonia is defined as changes of voice, difficulty speaking and pain on speaking.
- Presence of nausea is defined as yes if a patient feels nauseated in each period for at least 10 min.
- Presence of vomiting is defined as a presence of symptoms of throwing out or retching.
- Satisfaction is defined as patient satisfaction with the airway management.
- First-time intubating success is defined as successful airway device insertion at the first time
- Three-time intubating failure is defined as intubation failure after the 3rd attempt.
- Intubation difficulty is defined as scaling of the difficulty in insertion of airway device by the investigator

2.6 Research design

Randomized, patient and assessor-blinded, parallel-group clinical trial.

2.7 Research methodology

2.7.1 Population and sample

Target population

The ambulatory patients who were undergoing gynecologic laparoscopy.

Sample population

The ambulatory patients, scheduled for gynecologic laparoscopy at King Chulalongkorn Memorial Hospital who met the eligible criteria.

2.7.2 Inclusion criteria

- Female patients scheduled for elective ambulatory gynecologic laparoscopy who gave written informed consent.
- Age $\geq$ 18 yr, ASA physical status I-II.

2.7.3 Exclusion criteria

- Patients at risk of difficult mask ventilation.
- Patients at risk of difficult intubation (32).
- History of difficult intubation
- Modified mallampati class III or IV (Appendix 2), (33).
- Thyromental distance < 4 cm
- Interincisor gap < 2 cm
- BMI>35kg/m^2
- Patients at risk of aspiration (nonfasted ;- less than 2 hr after clear liquid and 6 hr after a light meal, gastro-esophageal reflux).
- Patients who had one of preoperative score other than zero for sore throat, dysphagia or dysphonia.
- Patients with upper airway lesion, infection, or oropharyngeal pathology.
- Patients with cardiovascular or respiratory disease, bleeding disorder.
- Patients refused to participate in the study.
- Patients who were not able to get a telephone interview at 24 hr postoperatively.
- Patients undergoing combined laparoscopic and other related and unrelated procedures.

2.7.4 Sample size estimation

The primary outcomes of the study are scores of sore throat comparing between PLMA and PSSC at the same period of 2 and 24 hours. Wilcoxon Mann-Whitney rank sum test for ordered categories was used for sample size calculation by N Query Advisor® Version 5.0 (Appendix 3), (34).

One study about scaling of severity of sore throat showed the data for PSSC as 9, 4, 2, 0 patients who gave scores from 0 to 3 (11) and those from PLMA study was 36, 5, 1, and 0 patients (24).

For 2 independent group, 2-sided type I error of 5%, and power of 95%, then the sample size should be 69 for each group.

2.7.5 Randomization and allocation concealment

The patients who met the eligible criteria were randomized in a 1:1 ratio to one of two treatment groups.

1. Profile Soft-Seal Cuff™ (PSSC)
2. LMA ProSeal™ (PLMA)

The randomization list was computer-generated random sequence. The allocation for airway management with PLMA or PSSC (by opening a sealed envelope) was shown only to the investigator, who gave an anesthesia before the period of induction. However, the allocation was blinded to the assessor. The outcome data were obtained by the same independent observer who was not informed about the airway technique.

2.7.6 Intervention

The patient was in lithotomy position with her head on a standard pillow 7 cm in height. Monitoring of blood pressure, oxygen saturation by pulse oximeter and EKG were applied. The anesthesia was given to the enrolled patients by only one and same anesthesiologist, who has more than 20 experiences on PLMA and 95% over all success rate.

Induction of anesthesia was by fentanyl 1 μg/kg, 20 mg lidocaine, 2-2.5 mg/kg propofol and 0.3 mg/kg atracurium intravenously. Maintenance was performed with 100-200 μg/kg/min propofol intravenously. The patient's lungs were ventilated with 100 % oxygen via a face mask for 3 minutes then the same anesthesiologist intubated the patient with a size 4 PLMA or 7.0-ID PSSC according to the allocation. A clear water-based gel was used for lubrication in all cases.

For PLMA, the insertion technique was identical to the recommended technique for the LMA, including neck flexion/head extension and full deflation of the cuff (5). Slight lateral approach will be used if resistance is felt in the oropharynx. The cuff will be inflated with room air to the manufacturer's recommended cuff pressure of 60 cm H_2O measured with a calibrated anaeroid manometer. Then the anesthetic circuit is connected and the patient's lungs are ventilated. The position of the device will be

checked and corrected to achieve square P_{ET} CO_2 waveform and adequate breathing flow at 3 liter/min, otherwise repositioning the device would be needed.

In the PSSC group, endotracheal intubation was applied under direct laryngoscopy. The cuff was inflated with 0.5 ml increment of air until no leakage of ventilated gas at 25 cm H_2O. Just-sealed cuff inflation was additionally needed if air leakage was detected during pneumoperitoneum.

For both groups, after the 3rd intubation failure, the other intervention would be used instead and the data was analyzed as intention to treat basis.

After we obtained the correct position, we performed an airway pressure leak test. We set a continuous gas flow (FGF) of 3 l/min with the adjustable pressure-limiting valve closed and the circuit was connected to the reservoir bag. The leak pressure was recorded when airway pressure reached a plateau. When the airway pressure reached beyond 35 cmH_2O, the test was finished.

After intubation, patient's lungs were ventilated with tidal volume (V_T) 10 ml/kg and rate 12/min of 66 % nitrous oxide in oxygen at 3 l/min flow rate. Higher flow needed to compensate air leakage was recorded. End tidal carbon dioxide ($P_{ET}CO_2$), Oxygen saturation (SpO_2), noninvasive blood pressure, and EKG were monitored. The inspired oxygen concentration was adjusted if SpO_2 < 95 %. If $P_{ET}CO_2$ was > 45 mmHg, then we managed this situation step by step as following, respiratory rate to be 14, then 16 breaths per min and then V_T to be 12 ml/kg. A period of 3 min was allowed between adjustments. For PLMA group, if SpO_2 was below 90 % or $P_{ET}CO_2$ above 50 mmHg during the procedure, the surgeon would release the gas from the abdominal cavity and PLMA was replaced with PSSC and recorded as ventilating failure. During the procedure, a gastric tube insertion might be needed for exposure achievement.

The PLMA or PSSC was removed at the end of surgery when the patient was able to open her mouth following the verbal command. Any bloody stain on the device upon removal, events of gastric decompression needed and the duration of anesthesia were recorded. During the postoperative period, patients would receive one gram of paracetamol orally, when it was requested for pain killer. At the second hour after extubation, the same assessor who was masked to the patients' group would follow the structure for assessment to evaluate the score of consciousness and to obtain the scores

of sore throat, dysphagia dysphonia, nausea, vomiting and abdominal pain (Appendix 4).

The patient was discharged after her post-anesthesia discharge scoring system (PADSS: Appendix 5) was more than 9 (35). Twenty-four hours after anesthesia, the masked assessor contacted the patient by telephoning to perform the same assessments as at 2 hours postoperatively including patient's satisfaction to the airway device.

2.7.7 Outcome measurement

Patient population

The patient population was defined as all patients who were randomized and received airway management by one of two airway devices.

Primary outcome variable

The primary outcome variable was 4-leveled score of sore throat (0-3) from no pain to severe pain. All patients gave pain score at 2 hr postoperatively.

Secondary outcome variables

- Four-leveled score of sore throat (0-3) at 24^{th} hr, for dysphagia and dysphonia from no symptom to severe symptom at 2^{nd} and 24^{th} hr postoperatively.
- Presence of nausea or vomiting at 2 and 24 hr postoperatively.
- Five-leveled satisfaction score for the airway management at 24 hr postoperatively.

Efficacy variables

- The leak pressure of PLMA by pressure leak test below 35 cmH_2O airway pressure.
- Numbers of patients who needed higher F_IO2 (> 0.33), various minute ventilation (MV10 x 12, 10 x 14, 10 x 16, 12 x 16 ml/kg x breath/min) and higher fresh gas flow (FGF > 3 l/min).
- Numbers of patients with 3-time intubation failure, first time intubation success and ventilating failure.

Cost minimization analysis

The average costs of PLMA combined with reused process per time was compared to the cost of PSSC.

2.7.8 Data collection

The following data were recorded

1. *Demographic data, baseline characteristics* :

These following data were recorded by the same investigator who intubated the patients

- Age (yr)
- Weight (kg), Height (cm), BMI (kg/m^2)
- Operative time from incision to wound closure (min)
- Scaling of intubation difficulty (0-2)
  - 0 = one attempt, no tactile resistance
  - 1 = one attempt, some tactile resistance
  - 2 = two or more attempts
- Detected blood on PLMA or PSSC (blood on device) [yes / no]
- Gastric decompression of the stomach (Suction needed) [yes / no]
- First time intubation success [yes / no]
- Three time intubation failure [yes / no]

Table1 Data collection of demographic data and baseline characteristics

Age	____	yr		
Weight	____	kg		
Height	____	cm		
BMI	____	kg/m^2		
1^{st} intubation success	Yes	[ ]	No	[ ]
3^{rd} intubation failure	Yes	[ ]	No	[ ]
Intubation difficulty	0 -2	[ ]		
blood on device	Yes	[ ]	No	[ ]
Suction needed	Yes	[ ]	No	[ ]
Operative time	____	min		

2. *Outcomes :*

These following data were obtained from each patient at the same period by the same assessor.

Patient side

- Sore throat at 2 and 24 hours postoperatively.

(Score 0-no pain, 1-mild pain, 2-moderate pain, 3-severe pain)

- Dysphagia at 2 and 24 hours postoperatively.

(Score 0-easily swallowing, 1-some degree of difficulty, 2-very difficult, 3-cannot swallow)

- Dysphonia at 2 and 24 hours postoperatively.

(Score 0-no voice change, 1-minimal change, 2-apparently change, 3-no voice)

- Nausea symptom at 2 and 24 hours postoperatively.

(Presence or absence)

- Vomiting at 2 and 24 hours postoperatively.

(Presence or absence)

- Satisfaction score by Likert scale at 24 hours postoperatively.

(Score 0-not satisfy at all, 1-not satisfy, 2-satisfy, 3-very satisfy, 4- most satisfy)

These following data were recorded by the same assessor.

- Postoperative stage of consciousness at 2 hr postoperatively (0-3)
  - 0 = does not respond
  - 1 = asleep, responds to touch and pain
  - 2 = asleep, responds to verbal command
  - 3 = fully awake, open eyes
- Verbal numerical pain score (score 0-10: no pain-the worst imaginable pain) for abdominal pain at 2 and 24 hours postoperatively.

Table 2 Data collection of outcomes, scores at 2nd and 24th hrs postoperatively

Sore throat (2,24 hr)	0 [ ]	1 [ ]	2 [ ]	3 [ ]	
Dysphagia (2,24 hr)	0 [ ]	1 [ ]	2 [ ]	3 [ ]	
Dysphonia (2,24 hr)	0 [ ]	1 [ ]	2 [ ]	3 [ ]	
Nausea (2,24 hr)	Yes [ ]		No [ ]		
Vomiting (2,24 hr)	Yes [ ]		No [ ]		
Pain (2,24 hr)	0 -10 [ ]				
Consciousness (2hr)	0 [ ]	1 [ ]	2 [ ]	3 [ ]	
Satisfaction (24 hr)	0 [ ]	1 [ ]	2 [ ]	3 [ ]	4 [ ]

Efficacy side

The same investigator observed the efficacy of each airway device as following:

- The leak pressure of PLMA (cmH_2O, maximum at 35 cmH_2O)
- Numbers of patients who need
  - $F_IO_2 > 0.33$
  - MV (V_T x f) > 10 x 12 ml/kg x breath/min
  - FGF > 3.0 l/min
- Ventilating failure (SaO2>95%, or $P_{ET}CO_2$<45 mmHg were not achieved [yes / no]

- Cost

The costs of the airway techniques were the costs of the airway devices combined with that of a disinfecting process by autoclave for a reusable PLMA.

Table 3 Data collection of efficacy of the airway devices

Leak pressure	____cmH_2O				
F_IO_2>0.33	Yes	[ ]	No	[ ]	
MV>10×12 ml/kg ×breath	Yes	[ ]	No	[ ]	
FGF>3 l/min	Yes	[ ]	No	[ ]	
Ventilation failure	Yes	[ ]	No	[ ]	
Number of time used of PLMA	____ times				

2.7.9 Data analysis

All data were analyzed as intention-to-treat basis. The demographic and baseline data were presented as mean (SD) or frequency as appropriate. Postoperative verbal numeric rating score of pain were presented as median and inter-quartile range. Some characteristics were related to throat discomfort; therefore the differences between the 2 groups were confounders of the study outcomes. These characteristics included intubation difficulty, bloody stain on device, gastric decompression, intubation failure and ventilating failure. Multivariable analysis was used to determine these relative contributions of different causes to the outcomes of throat discomfort.

Test of the objective end points.

Test of association was used to analyze the outcomes of two different techniques. Because the main outcome for answering the primary question were frequencies among the groups which had an ordering from 0-4, Chi squared test for trend was used to show differences between two groups to be related to the ordering. Therefore, Chi squared test for trend was employed to compare 4 grades of sore throat, dysphagia, dysphonia, and 5 grades of satisfaction between the two groups.Additionally,

data analysis was also performed between binary outcomes of nausea or vomiting and severity of sore throat by Chi squared test for trend. The test detected the association of the ordering of severity of sore throat and incidence of nausea or vomiting. However, regrouping may be required to get 80% of cells with expected frequencies greater than 5 and all with expected frequencies greater than 1. Fisher's exact test was an alternative approach for very small expected frequencies.

Test of the efficacy events

Leak pressure was reported as median and inter-quartile range because the data were censored at 35 cmH_20 according to the design of the study.

For other efficacy results, test for the association to the airway techniques by chi-squared test was used. These efficacy variables were numbers of patients who needed higher F_IO2 (>0.33), higher MV (>10x12 ml/kg x breath/min), higher FGF (>3.0 l/min) and patients who were suffered from ventilating failure and those from nausea or vomiting. Fisher's exact test was an alternative approach for very small expected frequencies.

Additionally, data analysis was performed between binary outcomes of nausea or vomiting and severity of sore throat by Chi squared test for trend. The test can detect the association of the ordering of severity of sore throat and incidence of nausea or vomiting.

Statistical analysis was performed by SPSS Program version 11.0

Table 4 Demographic data and baseline characteristics

Age	*Mean(SD)*
Weight	*Mean(SD)*
Height	*Mean(SD)*
BMI	*Mean(SD)*
Operative time	*Mean(SD)*
Conscious level	*Frequency (%)*
VNS of pain	*Median(inter-quartile range)*
Intubation difficulty	*Frequency (%)*
Bloody stain on device	*Frequency (%)*
Gastric decompression	*Frequency (%)*
Intubation failure	*Frequency (%)*
Intubation success	*Frequency (%)*
Patient side	
Sore throat	*Chi squared for trend*
Dysphagia	*Chi squared for trend*
Dysphonia	*Chi squared for trend*
Satisfaction	*Chi squared for trend*
Nausea/vomit-sore throat	*Chi squared for trend*
No. nausea or vomit	*Chi squared test*
Efficacy side	
$F_iO2 > 0.33$	*Chi squared test*
FGF > 3 l/min	*Chi squared test*
MV > 10 x12	*Chi squared test*
Ventilating failure	*Ch squared test*

2.7.10 Ethical consideration

All eligible patients received details of the study protocol and the investigator explained the protocol thoroughly to the patients which included possible complications from the technique of general anesthesia. All patients had to give written informed consent before randomization.

General anesthesia with neuromuscular blockade and controlled ventilation provides better surgical condition for gynecologic laparoscopy. Formerly, endotracheal intubation is a recommended airway technique for any kind of laparoscopy. Recently, laryngeal mask airway has gained popularity and is becoming an alternative airway device. Many studies reported about LMA benefits in the aspect of less throat symptoms and patients' abilities to gain their normal activities sooner. Besides, sympathetic over-activities during endotracheal extubation can be avoided. Many studies confirmed that PLMA is an effective alternative to endotracheal intubation for general anesthesia (6, 7) including that in gynecologic laparoscopy (36). Regarding safety, there still has been no report of higher incidence of gastric aspiration in PLMA than endotracheal tube even by a sensitive technique to detect aspiration (37, 38). Additionally, from a meta-analysis, there is no evidence of higher risk of aspiration in LMA than endotracheal group (39).

2.7.11 Limitation

This study was limited to the patients who received explanation and clearly understood the definition of throat discomfort and its score of severity. The results of this study would be limited to female patients undergoing ambulatory laparoscopic procedures.

Since the study of LMA on morbidly obese patients is still limited, therefore, this study excluded the patients with BMI>35 kg/m^2. The patients in this group are more likely to have reduced thoracic compliance, increased inspiratory resistance and greater risk of regurgitation. Even the PLMA allows for ventilation with higher airway pressure, however, achieving the proper placement is technically demanding (40).

2.7.12 Implication

The information obtained from this study would provide a technique of choice for airway management in ambulatory gynecologic laparoscopy, in which general anesthesia has gained its popularity to become a routine practice instead of conscious sedation in the near future.

CHAPTER 3

RESULTS

3.1 Basic characteristics of patients and baseline data

One hundred and thirty-eight patients were included in the study. All these following data were recorded as baseline data: age (yrs) body weight (kg), height (cm), body mass index (BMI, kg/m^2), operative time (min), and type of surgical procedure (Table 5). All the procedures were successfully undertaken and the surgical exposures were satisfied without gastric decompression needed. All the patients were fully awake (score of consciousness =3) at the time of the 2^{nd} hour evaluation. The data at the 24^{th} hour postoperation of 1 patient in PSSC group was missed since the investigator was not able to contact the patient by telephone interview.

Table 5 Patients' characteristics and operation information

Airway	PSSC N=69	PLMA N=69
Age (yrs)	34.32 (4.06)	34.63 (3.83)
Weight (kg)	54.35 (8.21)	52.82 (7.86)
Height (cm)	156.43 (5.29)	156.94 (5.23)
BMI (kg/m^2)	22.20 (2.99)	21.47 (3.28)
Operative Time (min)	32.03 (12.04)	30.20 (8.64)
Procedure* LDx/LTR	63/6 (91.30/8.70%)	66/3 (95.65/4.35%)

Value are expressed as mean (SD)

*P=0.493, Chi^2 Fisher's Exact test

LDx: diagnostic laparoscopy

LTR: laparoscopic tubal resection

First-time intubation success was found in almost all of the cases, except 1 patient in PLMA and 2 in PSSC group. One of these two in PSSC, intubation was failed after the 3^{rd} time because of laryngoscope view grade IV. Therefore, this patient was crossed-over to PLMA and 1^{st} time intubation success was achieved. The degree of intubation

difficulty and airway trauma were not statistically different between the 2 groups. Gastric decompression was done only in PLMA group for checking the position of the device or decompression of the stomach. The 3-score; i.e. fully awake, was the only result of the score of consciousness, and the abdominal pain scores both in early and late postoperative period also were not statistically significant (Table 6).

Table 6 Intubating conditions and postoperative pain

	PSSC N=69	PLMA N=69	Total	p
Intubation difficulty				
0	55 (79.7%)	54 (78.3%)	109 (79.0%)	0.409 [T]
1	12 (17.4%)	12 (17.4%)	24 (17.4%)	
2	2 (2.9%)	3 (4.3%)	5 (3.6%)	
Blood on device	2 (2.9%)	5 (7.2%)	7 (5.1%)	1.000 [F]
Gastric decom-pression	0	5 (7.2%)	5 (3.6%)	1.000 [F]
Intubation failure	(1) (1.4%)	0	1 (0.72%)	1.000 [F]
Intubation success	67 (97.10%)	68 (98.6%)	135 (97.83%)	1.000 [F]
Pain(0-10)				
2 hrs	2 (1-3)	2 (1.5-4)		0.293 [T]
24 hrs	1.5 (1-3)	2 (1-2)		0.546 [T]

Value are expressed as frequencies, percentages, median (interquatile range)

[T] Chi^2 Linear by Linear Association

[F] Chi^2 Fisher's Exact

3.2 Primary outcome analysis

Severity of early sore throat

For the sample of 138 patients, the Chi squared test for trend revealed that the study devices and scores of sore throat were statistically significantly associated by ordering (P=0.016,Chi^2 Linear by Linear Association) (Table 7).

If the sore throat score > 0 (score 1 and 2) is categorized as the symptom suffering group, we can estimate the ratio of relative risk to be 1.609 (1.079, 2.398 for 95 % CI) for PSSC compared with PLMA.

Table 7 Throat discomforts at early period (2nd hr postoperatively)

	PSSC (%) N=69	PLMA (%) N=69	Total (%) N=138	P
Sore throat				
0	32 (46.4)	46 (66.7)	78 (56.5)	
1	31 (44.9)	21 (30.4)	52 (37.7)	.016[T]
2	6 (8.7)	2 (2.9)	8 (5.8)	
3	0	0	0	
Dysphagia				
0	31 (44.9)	39 (56.5)	70 (50.7)	
1	35 (50.7)	29 (42.0)	64 (46.4)	.168[T]
2	3 (4.3)	1 (1.4)	4 (2.9)	
3	0	0	0	
Dysphonia				
0	8 (11.6)	23 (33.3)	31 (22.5)	
1	53 (76.8)	42 (60.9)	95 (68.8)	.003[T]
2	8 (11.6)	4 (5.8)	12 (8.7)	
3	0	0	0	

Value are expressed as frequencies, percentages

[T] Chi^2 Linear by Linear Association

[C] Chi^2 Continuity Correction

3.3 Secondary outcome analysis

Severity of late sore throat, early and late dysphagia, and dysphonia.

In the early period, Chi squared test for trend revealed that the study devices and scores of dysphonia were significantly associated by ordering ($p = 0.003$, Chi^2 Linear by Linear Association) (Table 7). The relative risk for those who had dysphonia symptoms (score 1, 2) was 1.326 (1.099, 1.599 for 95 % CI) in PSSC compared with PLMA. In spite of these findings, the frequencies of the patients compared between these 2 groups, who exhibited late symptoms of sore throat, dysphonia, and both early and late symptoms of dysphagia were not found to be significantly different (Table 7 and 8).

Table 8 Throat discomforts at late period (24th hr postoperatively)

	PSSC (%) N=68	PLMA (%) N=69	Total (%) N=137	P
Sore throat				
0	51 (75.0)	52 (75.4)	103 (75.2)	
1	15 (22.1)	16 (23.2)	31 (22.6)	.749[T]
2	1 (1.5)	1 (1.4)	2 (1.5)	
3	1 (1.5)	0	1 (0.7)	
Dysphagia				
0	56 (82.4)	57 (82.6)	113 (82.5)	
1	10 (14.7)	12 (17.4)	22 (16.1)	0.595[T]
2	1 (1.5)	0	1 (0.7)	
3	1 (1.5)	0	1 (0.7)	
Dysphonia				
0	49 (72.1)	58 (84.1)	107 (78.1)	
1	18 (26.5)	11 (15.9)	29 (21.2)	0.080[T]
2	1 (1.5)	0	1 (0.7)	
3	0	0	0	

Value are expressed as frequencies, percentages

[T] Chi^2 Linear by Linear Association

[C] Chi^2 Continuity Correction

Predicting binary outcome of sore throat

Considering the explanatory factors for sore throat, airway devices with PSSC and difficult intubation were both significant factors (p=.016 for both factors, comparing with PLMA) (Table 9).

Table 9 Binary logistic regression analysis : Predicting binary outcome of sore throat from the study devices and intubation difficulty index

	PSSC	Intubation difficulty score			Constant
		0	1	2	
B	.875		1.178	-.901	-.891
S.E.	.363		.488	1.153	.283
Wald	5.818	6.759	5.841	0.610	9.872
df	1	2	1	1	1
Sig.	0.016	0.034	0.016	0.435	0.002
Exp (B)	2.399		3.249	0.406	0.410

Proportions of nausea and vomiting

No difference of the proportion of nausea between the 2 groups (P = 0.843 and 0.493 in early and late periods) (Table 10). But the patients with higher scores of sore throat had significantly higher incidence of nausea in the early, but not in the late postoperative period (P = 0.018, Chi^2 Linear by Linear Association) (Table 11).

Four patients had vomiting in early postoperative period, but statistical analysis was not significant both in early and late periods (P = 0.120, 1.000 by Chi^2 with Continuity Correction. and Fisher's Exact test) (table 10).

Table 10 Postoperative nausea, vomiting, and satisfaction at 2nd and 24th hrs

	PSSC	PLMA	Total	P
Nausea				
2nd hr	16 (23.2%)	18 (26.1%)	34 (24.6%)	.843[C]
	N=69	N=69	N=138	
24th hr	3 (4.4%)	6 (8.7%)	9 (6.6%)	.493[F]
	N=68	N=69	N=137	
Vomiting				
2nd hr	4 (5.8%)	0	4 (2.9%)	.120[C]
	N=69	N=69	N=138	
24th hr	0	1 (1.4%)	1 (0.7%)	1.000[F]
	N=68	N=69	N=137	
Satisfaction				
(PSSC n=68,				
PLMA n=69)	0	0	0	
0	0	0	0	
1	7 (10.3%)	3 (4.3%)	10 (7.3%)	0.302[T]
2	29 (42.6%)	30 (43.5%)	59 (43.1%)	
3	32 (47.1%)	36 (52.2%)	68 (49.6%)	
4				

Value are expressed as frequencies, percentages

[F] Chi^2 Fisher's Exact

[C] Chi^2 Continuity Correction

[T] Chi^2 Linear by Linear Association

Table 11 Incidence of nausea in early (2nd hr) and late (24th hr) periods among three-level scores of sore throat

Sore throat	Score 0	Score 1	Score 2	Total	P
Nausea (early)					
Presence	12 (15.4%)	20 (38.5%)	2 (25.0%)	34 (24.6%)	
Absence	66 (84.6%)	32 (61.5%)	6 (75.0%)	104 (75.4%)	0.018[T]
Total	78 (100.0%)	52 (100.0%)	8 (100.0%)	138 (100.0%)	
Nausea (late)					
Presence	3 (3.8%)	5 (9.8%)	1 (12.5%)	9 (6.6%)	
Absence	75 (96.2%)	46 (90.2%)	7 (87.5%)	128 (93.4%)	0.158[T]
Total	78 (100.0%)	51 (100.0%)	8 (100.0%)	137 (100.0%)	

Value are expressed as frequencies, percentages

[T] Chi^2 Linear by Linear Association

No one gave unsatisfied scores (score 0 and 1) and among the scores ranged from score 2 to 4 were not significantly different between these two devices (table 10).

We found the significant association between satisfaction and the numbers of patients suffering from both sore throat and dysphonia (P = 0.042 and 0.042 respectively, Chi^2 Linear-by-Linear Association) (table 12).

Table 12 Association of the satisfaction scores and throat discomforts

	Satisfaction score				
	0	1	2	3	4
Sore throat score					
0	0	0	2 2.6%	33 42.3%	43 55.1%
1	0	0	7 13.7%	22 43.1%	22 43.1%
2	0	0	1 12.5%	4 50.0%	3 37.5%
total	0	0	7.3%	43.1%	49.6%
p			.042 [T]		
Dysphonia score					
0	0	0	1 3.3%	10 33.3%	19 63.3%
1	0	0	7 7.4%	43 45.3%	45 47.4%
2	0	0	2 16.7%	6 50.0%	4 33.33%
total	0	0	7.3%	43.1%	49.6%
p			.042 [T]		

Value are expressed as frequencies, percentages

[T] Chi^2 Linear by Linear Association

Efficacy variables

Leak pressure of the PLMA had median value at 23 cmH_2O (20, 25 at 25, 75 percentiles). Increasing of minute ventilation and total fresh gas flow were needed in one

case of PLMA to compensate the gas leakage during ventilation control. However, no case of $SpO_2 \leq 95$ %, $P_{ET}CO_2 > 45$ mmHg or $F_IO_2 > 0.33$ was found in both groups.

Cost minimization analysis

The PLMA was guaranteed for 40 uses per each. Each PLMA costs 10,800 Bht, therefore PLMA maximum cost should be 10,800/40 = 270 Bht/1 use

The disinfection process by autoclave including manpower and chemical substance at King Chulalongkorn Memorial Hospital at the period of the study was 215.08 Bht/40 pieces. Therefore, 1 PLMA costs 5.38 Bht/1 use. Therefore, the maximal total cost of PLMA was 275.38 Bht/1 use for 40-time uses, comparing with 117.70 Bht/ 1 use of disposable PSSC.

CHAPTER 4

DISCUSSION

Irritation of the subglottic structures by endotracheal tube usually results in sore throat and dysphonia by compression effect on glottic and subglottic mucosal structure. Comparing to PLMA, by Chi-square, Linear by Linear Association, the proportions of sore throat and dysphonia trended to be rising towards the direction of worse conditions in the PSSC group. By calculation in this study, the risk will be 1.6 times higher for sore throat and 1.3 times higher for dysphonia, when PSSC was compared with PLMA. However, no statistical significance was found for dysphagia between these two devices. This finding does not support the study of those who reported more dysphagia in the LMA group than the endotracheal tube group. Our study found that PSSC, comparing to PLMA, produced higher percentages of patients who suffered from early sore throat (53.6% vs 33.3%) and dysphonia (87.9% vs 66.7%). Remarkably, the figures of the patients with positive symptoms of sore throat and dysphonia were higher than those from the study of Higgins, Chung, and Mezei for endotracheal tube and classic LMA (3). The explanation of these outcomes is the higher cuff pressure of PSSC which is needed for adequate ventilation in high intraperitoneal pressure. Another explanation may be the fixed size of 7.0 French PSSC, which might not fit properly for some patients. Higher cuff pressure could be required for the airway seal after using a too small size of an endotracheal tube and might provoke more compression effect.

According to this study, either the endotracheal intubation or PLMA insertion was performed under the half of the recommended dose of atracurium for intubation. The rationale for this reduced dose was to avoid the problems related to unsuccessful reversal after a short period procedure. This smaller intubating dose might have an influence on the incomplete glottic relaxation and endotracheal tube bucking during extubation, therefore, this could affect the outcomes of throat symptoms. However, the index of intubation difficulty did not show any statistical difference.

Comparing dysphagia after PLMA to that after PSSC, no statistical difference was found in spite of the compressive effect of the PLMA cuff on the posterior pharynx

and the entry of esophagus. By using the constant cuff pressure of PLMA at 60 cmH_2O, this set pressure might have little effect on the muscle group of swallowing, and as a consequence, might also have little effect on dysphagia.

Glottic and subglottic tissue trauma subsided spontaneously within 1 day. As a result, we could not find any statistical difference of throat symptoms between these 2 groups at the 24^{th} hour postoperatively.

In clinical practice, types of airway devices and difficult intubation can induce mucosal injuries and play an important role in sore throat. By binary logistic regression analysis, an airway technique with PSSC and traumatic intubation detected by tactile resistance (score-1 intubation) were the associated risk factors with sore throat (both p=.016, coefficient=0.875, odds ratio= 2.40 for PSSC, and coefficient=1.178, odds ratio= 3.25 for tactile resistance. However, a small number of the cases of score-2 intubation might be a cause of statistical insignificance.

Since nauseated feeling can be affected by many factors, we didn't find any difference under these randomized controlled groups. There are some postulations for this negative difference. First, this may be under the circumstances of high risk procedures to PONV, and this might have concealed the direct effect of airway devices themselves. Second, the sample size is too small to detect this significance of nauseated feeling, since it was calculated for the research question of sore throat, which had higher incidence.

Considering the influence of sore throat on PONV, there was a significant association between sore throat scores and proportion of nauseated patients in the early period (P=0.018, Linear-by-Linear Association) (Table 11), which agrees with the study of Wang et al.(2). Clinically, we found higher incidence of laryngeal secretion after PSSC. Subglottic and glottic stimulation by the endotracheal cuff might provoke stronger nerve impulse and induced vomiting in the early postoperative period. Unfortunately, this incidence of vomiting (4 patients in PSSC group in early period) was too low to demonstrate any statistical difference.

The results showed that satisfaction scores to the airway devices were in the satisfied side (score 2-4), which it seems likely that these throat symptoms might not be of much concern. Satisfaction evaluation would be more useful if it was evaluated in the

aspects of physical and functional performances. Considering among these scores, the patients were more satisfied with less severe throat symptoms (Table12).

Considering the efficacy and safety of PLMA when compared to PSSC, the result of this study supports using a laryngeal mask airway as an alternative management in difficult airway algorithm. PLMA was easily placed (difficulty index = 0) and effectively used for ventilation in one patient with grade-3 laryngoscopic view after failed PSSC intubation.

Under the condition of an anesthesiologist experienced in both airway devices, PLMA was comparable to PSSC in the aspects of the incidence of airway injuries, the ease and the successful rate of intubation. For the efficacy of the devices, PLMA had some events of air leakage when peak airway pressure was reached. By the limited cuff pressure of PLMA at 60 cmH_2O, a leak sometimes appeared at the peak airway pressure during pneumoperitoneum. However, most of this condition did not need increments of FiO_2 or gas flow and gastric decompression, except for one patient with malposition of PLMA. The study of Natalini, Lanza, et al. found that the leak fraction of the tidal volume (V_T inspired-V_T expired/ V_T inspired) was 7 ± 4% with the PLMA in gynecologic laparoscopy. Otherwise, position correction or using the appropriate device must be considered to allow effective mechanical ventilation delivery during laparoscopic surgery and to reduce the aspiration risk in the malposition (36).

The maximal BMI from our study was 33.3 kg/m^2. Natalini, Franceschetti, et al. recommended the safely use of PLMA in patient with BMI under 35 Kg/m^2 (24). Higher airway pressure in obese patients might cause more air leak during positive pressure ventilation through PLMA, therefore, the requirement of over 60 cmH_2O cuff pressure might be necessary. According to our study, it is important to mention that most of the patients were lean females with the averaged BMI of 22.20±2.99 kg/m^2. Therefore, further study is probably required to investigate the safe use of PLMA in the obese patients.

Since there were comparable outcomes of either clinical effectiveness of respiratory control or postoperative satisfaction scores between these two techniques, we performed economic analysis by cost minimization. Considering the cost minimization under the 40-time-guaranteed use of PLMA, it costs more expensive than PSSC until after the 96^{th} time of PLMA use. After that, the PLMA cost will be less than

PSSC. To estimate the costs for the benefit gains of less throat symptoms using PLMA instead of PSSC, 157.68 Bht was an additional cost for the first 40-time uses of PLMA or 10,800/n + 5.38 – 117.70 Bht when n is the number of over 40-time uses. However, many other intangible costs and benefits had not been included in the calculation. Some of these were the morbidity of intubation or insertion failure of the devices, and the recovery of patient's speech function for both normal livings and working activities. From our study, it is suggested that PLMA may have advantages of minimal throat symptoms in the patients who expect to gain their speech function earlier. Additionally, it might be the airway technique of choice for those who are under a prediction of difficult airway.

However, to select the appropriate airway device for general anesthesia in ambulatory gynecologic laparoscopy, patient's safety, the efficacy of the technique and cost-effectiveness should be taken into account. For its safety and efficacy, this study was limited only to patients who had no risk of pulmonary aspiration, morbid obesity, difficult airway and pulmonary disease. The potential risk of pulmonary aspiration should be noticed especially when the proper position of PLMA cannot be achieved. Additionally, the comparable effectiveness of PLMA in this study was confined only in the short diagnostic laparoscopy. In the cost-effectiveness aspect, higher cost of PLMA should be weighed against its reduction of sore throat and dysphonia in the early postoperative period. Thus, all of these factors must be considered including patient's preference and the policy of the health care provider.

Conclusion

Comparing PLMA with PSSC, PLMA caused lower incidence and severity of sore throat and dysphonia, but not dysphagia, in early postoperative period comparing with PSSC. However, it did not influence the outcomes of dysphagia, nausea, vomiting and satisfaction. Its efficiency and safety were comparable to PSSC and it can be used as an alternative airway technique for general anesthesia in ambulatory gynecologic procedure under economic consideration.

REFERENCES

1. Macario A, Weinger M, Carney S, Kim A. Which clinical anesthesia outcomes are important to avoid? The perspective of patients. Anesth Analg 1999 Sep;89(3):652-8.
2. Wang JJ, Ho ST, Lee SC, Liu YC, Liu YH, Liao YC. The prophylactic effect of dexamethasone on postoperative nausea and vomiting in women undergoing thyroidectomy: a comparison of droperidol with saline. Anesth Analg. 1999 Jul;89(1):200-3.
3. Higgins PP, Chung F, Mezei G. Postoperative sore throat after ambulatory surgery. Br J Anaesth. 2002 Apr;88(4):582-4.
4. Rieger A, Brunne B, Hass I, Brummer G, Spies C, Striebel HW, Eyrich K. Laryngo-pharyngeal complaints following laryngeal mask airway and endotracheal intubation. J Clin Anesth. 1997 Feb;9(1):42-7.
5. Brimacombe J, Keller C. The ProSeal laryngeal mask airway. Anesthesiol Clin North America. 2002 Dec;20(4):871-91.
6. Maltby JR, Beriault MT, Watson NC, Liepert DJ, Fick GH. LMA-Classic(TM) and LMA-ProSeal(TM) are effective alternatives to endotracheal intubation for gynecologic laparoscopy: [Le ML Classique(TM) et le ML ProSeal(TM) peuvent remplacer efficacement l'intubation endotracheale pour la laparoscopie gynecologique]. Can J Anaesth. 2003 Jan;50(1):71-7.
7. Maltby JR, Beriault MT, Watson NC, Liepert D, Fick GH. The LMA-ProSeal is an effective alternative to tracheal intubation for laparoscopic cholecystectomy. Can J Anaesth. 2002 Oct;49(8):857-62.
8. Combes X, Schauvliege F, Peyrouset O, Motamed C, Kirov K, Dhonneur G, Duvaldestin P. Intracuff pressure and tracheal morbidity: influence of filling with saline during nitrous oxide anesthesia. Anesthesiology. 2001 Nov;95(5):1120-4.
9. Tu HN, Saidi N, Leiutaud T, Bensaid S, Menival V, Duvaldestin P. Nitrous oxide increases endotracheal cuff pressure and the incidence of tracheal lesions in anesthetized patients. Anesth Analg. 1999 Jul;89(1):187-90.

10. al-Shaikh B, Jones M, Baldwin F.Evaluation of pressure changes in a new design tracheal tube cuff, the Portex Soft Seal, during nitrous oxide anaesthesia. Br J Anaesth. 1999 Nov;83(5):805-6.
11. Karasawa F, Mori T, Okuda T, Satoh T. Profile soft-seal cuff, a new endotracheal tube, effectively inhibits an increase in the cuff pressure through high compliance rather than low diffusion of nitrous oxide. Anesth Analg. 2001 Jan;92(1):140-4.
12. Burgard G, Mollhoff T, Prien T. The effect of laryngeal mask cuff pressure on postoperative sore throat incidence. J Clin Anesth. 1996 May;8(3):198-201.
13. Brimacombe J, Holyoake L, Keller C, Barry J, Mecklem D, Blinco A, Weidmann K. Emergence characteristics and postoperative laryngopharyngeal morbidity with the laryngeal mask airway: a comparison of high versus low initial cuff volume. Anaesthesia. 2000 Apr;55(4):338-43.
14. Ouellette RG. The effect of nitrous oxide on laryngeal mask cuff pressure. AANA J. 2000 Oct;68(5):411-4.
15. McHardy FE, Chung F. Postoperative sore throat: cause, prevention and treatment. Anaesthesia. 1999 May;54(5):444-53.
16. Harding CJ, McVey FK. Interview method affects incidence of postoperative sore throat. Anaesthesia. 1987 Oct;42(10):1104-7.
17. Brimacombe J, Holyoake L, Keller C, Brimacombe N, Scully M, Barry J, Talbutt P, Sartain J, McMahon P. Pharyngolaryngeal, neck, and jaw discomfort after anesthesia with the face mask and laryngeal mask airway at high and low cuff volumes in males and females. Anesthesiology. 2000 Jul;93(1):26-31.
18. Apfel CC, Roewer N, Korttila K. How to study postoperative nausea and vomiting. Acta Anaesthesiol Scand. 2002 Sep;46(8):921-8.
19. Brimacombe J. The advantages of the LMA over the tracheal tube or facemask: a meta-analysis. Can J Anaesth. 1995 Nov;42(11):1017-23.
20. Keller C, Brimacombe J. Bronchial mucus transport velocity in paralyzed anesthetized patients: a comparison of the laryngeal mask airway and cuffed tracheal tube. Anesth Analg. 1998 Jun;86(6):1280-2.
21. Chandler M. Tracheal intubation and sore throat: a mechanical explanation. Anaesthesia. 2002 Feb;57(2):155-61.

22. Asai T, Howell TK, Koga K, Morris S. Appropriate size and inflation of the laryngeal mask airway.Br J Anaesth. 1998 Apr;80(4):470-4.

23. Asai T, Murao K, Yukawa H, Shingu K.Re-evaluation of appropriate size of the laryngeal mask airway. Br J Anaesth. 1999 Sep;83(3):478-9.

24. Natalini G, Franceschetti ME, Pantelidi MT, Rosano A, Lanza G, Bernardini A. Comparison of the standard laryngeal mask airway and the ProSeal laryngeal mask airway in obese patient.Br J Anaesth. 2003 Mar;90(3):323-6.

25. Brain AI, Verghese C, Strube P, Brimacombe J. A new laryngeal mask prototype. Preliminary evaluation of seal pressures and glottic isolation. Anaesthesia. 1995 Jan;50(1):42-8.

26. Brimacombe J, Keller C. The ProSeal laryngeal mask airway: A randomized, crossover study with the standard laryngeal mask airway in paralyzed, anesthetized patients. Anesthesiology. 2000 Jul;93(1):104-9.

27. Holloway RH, Hongo M, Berger K, McCallum RW. Gastric distention: a mechanism for postprandial gastroesophageal reflux. Gastroenterology. 1985 Oct;89(4):779-84.

28. Brimacombe J, Keller C. Does efficacy of seal and fibreoptic view change during anaesthesia with the laryngeal mask airway: a comparison of oxygen and oxygen-nitrous oxide gas mixtures. Acta Anaesthesiol Scand. 2000 Nov;44(10):1258-60.

29. Mark DA. Protection from aspiration with the LMA-ProSeal(TM) after vomiting: a case report: [La protection contre l'aspiration avec le ML-ProSeal(TM) apres des vomissements : une etude de cas]. Can J Anaesth. 2003 Jan;50(1):78-80.

30. C K Koay. A case of aspiration using the Proseal LMA. Anaesth Intensive Care. 2003 Feb; 31(1)

31. Macario A, Chang PC, Stempel DB, Brock-Utne JG.A cost analysis of the laryngeal mask airway for elective surgery in adult outpatients. Anesthesiology. 1995 Aug;83(2):250-7.

32. Randell T. Prediction of difficult intubation. Acta Anaesthesiol Scand. 1996 Sep;40(8 Pt 2):1016-23.

33. Samsoon GLT, Young JRB. Difficult tracheal intubation: a retrospective study. Anaesthesia 1987; 42: 487–90.

34. Kolassa J. A comparison of size and power calculation for Wilcoxon statistics for ordered categorical data. Statistics in medicine 1995;14:1577-81.

35. Chung F. Discharge criteria—a new trend. Can J Anaesth 1995;42: 1056–8

36. Natalini G, Lanza G, Rosano A, Dell'Agnolo P, Bernardini A. Standard laryngeal Mask Airway™ and LMA-ProSeal™ during laparoscopic surgery. J Clin Anesth. 2003 September; 15(6):428-432.

37. Owens TM, Robertson P, Twomey C, Doyle M, McDonald N, McShane AJ. The incidence of gastroesophageal reflux with the laryngeal mask: a comparison with the face mask using esophageal lumen pH electrodes. Anesth Analg 1995 May;80(5):980-4.

38. Keller C, Brimacombe J, Kleinsasser A, Loeckinger A. Does the ProSeal laryngeal mask airway prevent aspiration of regurgitated fluid? Anesth Analg. 2000 Oct;91(4):1017-20

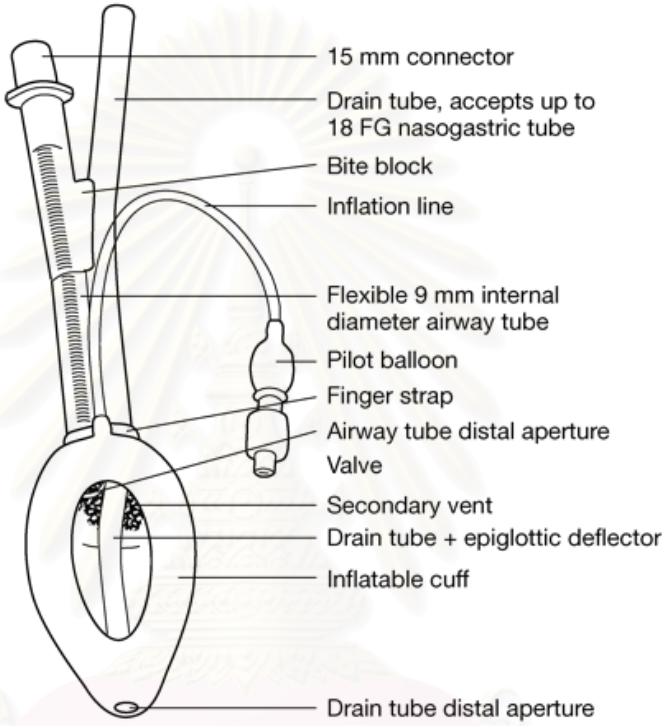
39. Brimacombe JR, Berry A. The incidence of aspiration associated with the laryngeal mask airway: a meta-analysis of published literature. J Clin Anesth. 1995 Jun;7(4):297-305.

40. Cooper RM.The LMA, laparoscopic surgery and the obese patient - can vs should: Le ML, la chirurgie laparoscopique et le patient obese - pouvoir vs devoir. Can J Anaesth. 2003 Jan;50(1):5-10.

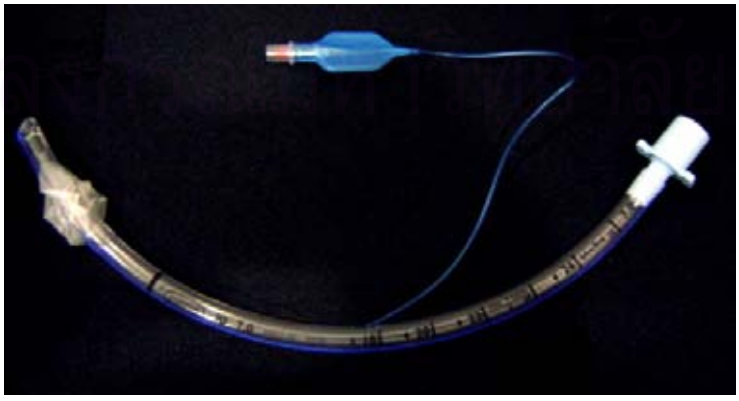
APPENDICES

APPENDIX 1

The LMA- ProSeal™ (PLMA : the Laryngeal-Mask Company, Henley-on-Thames, UK)



The Profile Soft-Seal Cuff ™ (PSSC: Sims Portex, Kent, UK)



APPENDIX 2

The modified Mallampati test for the classification of the oropharyngeal view

Class I = soft palate, fauces, uvula, and pillars seen

Class II = soft palate, fauces, and uvula seen

Class III = soft palate and base of uvula seen

Class IV = soft palate not visible

APPENDIX 3

Size and power calculations for the Wilcoxon Statistic for ordered categorical data

Kolassa J. A . Statistics in medicine 1995;14:1577-81.

Suppose **N** represents counts in a two-way $2 \times d$ table, with rows labelled E and C, and columns corresponding to ordered categories and labelled with integers from 1 to d. Suppose that each row represents an independent multinomial experiment with number of trials $n_{l\cdot} = \sum_j n_{lj}$ and cell probabilities π_{lj} for $l = E$ or C and $j = 1, \ldots, d$; that is, π_{lj} represents the probability of falling in column j conditional on being in row l. For example, π_{E1} is the probability of falling in the first category, conditional on falling into the experimental group. For $i = 1, \ldots, d-1$, suppose the model of McCullagh,[2] with all odds ratios set equal:

$$\theta = \log\left(\sum_{j=1}^{i} \pi_{Ej}\right) + \left(\sum_{j=i+1}^{d} \pi_{Cj}\right) - \log\left(\sum_{j=1}^{i} \pi_{Cj}\right) - \log\left(\sum_{j=i+1}^{d} \pi_{Ej}\right), \tag{1}$$

and with marginal expectations $n_{E\cdot}\pi_{Ej} + n_{C\cdot}\pi_{Cj}$ held fixed for $j = 1, \ldots, d$.

Whitehead[1] motivates the score test statistic for testing $\theta = 0$: $S = \sum_{i=1}^{d}(U_{Ci} - L_{Ci})n_{Ei}$, where $L_{li} = \sum_{j=1}^{i-1} n_{lj}$ and $U_{li} = \sum_{j=i+1}^{d} n_{lj}$ for $l = E$ or C, approximates the null variance of S by $\hat{\sigma}_W^2 = n_{E\cdot}n_{C\cdot}(n_{E\cdot} + n_{C\cdot})(1 - \sum_i \hat{\pi}_{i\cdot}^3)$, and approximates the alternative mean and variance by $\theta\hat{\sigma}_W^2$, and $\hat{\sigma}_W^2$. Let Φ be the normal distribution function, and let $z_{1-\alpha}$ satisfy $\Phi(z_{1-\alpha}) = 1 - \alpha$. Then

$$\hat{\sigma}_W z_{1-\alpha} \tag{2}$$

is the approximate upper critical value for a one-sided test of size α. An approximation of the type II error β for the one-sided test is $\beta = \Phi((\hat{\sigma}_W z_{1-\alpha} - \theta\hat{\sigma}_W^2)/\hat{\sigma}_W) = \Phi(-z_\alpha - \theta\hat{\sigma}_W)$. Hence $z_\beta = -z_\alpha - \theta\hat{\sigma}_W$, and approximately

$$(z_\beta + z_\alpha)/\hat{\sigma}_W = \theta. \tag{3}$$

Whitehead[4] earlier suggested an alternative approximate variance $\hat{\sigma}_W^2 = S^2/(n_{\cdot\cdot} + 2) + Q(n_{\cdot\cdot} + 1)/(n_{\cdot\cdot} + 2)$, where $n_{\cdot\cdot} = n_{C\cdot} + n_{E\cdot}$, $n_{\cdot j} = n_{\cdot J} + n_{\cdot j}$, and

$$Q = \sum_{i=1}^{d} (n_{Ei}(n_{C\cdot} - n_{Ci}) + n_{Ei}n_{Ci}(n_{\cdot\cdot} - n_{\cdot i}) + 2(n_{Ei}U_{Ci}L_{Ci} + n_{Ci}U_{Ei}L_{Ei})).$$

APPENDIX 4

Patient interview for assessment of throat discomfort

เนื่องจากขณะนี้ การดมยาสลบสำหรับการส่องกล้องทางหน้าท้องได้เสร็จสิ้นลงแล้วอย่างปลอดภัย ขอความกรุณาให้ท่านสละเวลาสำหรับการประเมินผลอาการไม่สบายในลำคอหลังการใส่ท่อหายใจ โดยขอให้ท่านประเมินความรุนแรงของอาการ โดยการให้คะแนนดังต่อไปนี้

1. อาการเจ็บคอ ซึ่งเป็นอาการที่ท่านรู้สึกเจ็บระคายหรือรู้สึกไม่สบายในลำคอ เมื่อท่านไม่ได้อยู่ในระหว่างกลืนน้ำลายหรือกลืนน้ำ โดยแบ่งตามความรุนแรงดังนี้

   0 = ไม่มีอาการเลย

   1 = มีอาการเล็กน้อย

   2 = มีอาการปานกลาง

   3 = มีอาการมาก

2. อาการกลืนลำบาก ซึ่งเป็นอาการที่ท่านรู้สึกเจ็บ, ระคาย หรือรู้สึกไม่สบายในลำคอ ขณะที่ท่านกลืนน้ำลายหรือกลืนน้ำ โดยแบ่งตามความรุนแรงดังนี้

   0 = กลืนได้ง่ายเหมือนปกติ

   1 = กลืนลำบากเล็กน้อย

   2 = กลืนลำบากมาก

   3 = กลืนเกือบไม่ได้ หรือกลืนไม่ได้เลย

3. อาการเสียงแหบ ซึ่งเป็นอาการที่ท่านรู้สึกว่ามีการออกเสียงที่ผิดปกติไปจากเดิมก่อนการผ่าตัด โดยแบ่งตามความรุนแรงดังนี้

   0 = เหมือนปกติ ไม่มีการเปลี่ยนแปลง

   1 = เสียงเปลี่ยนหรือแหบเล็กน้อย

   2 = เสียงเปลี่ยนหรือแหบชัดเจน

   3 = เสียงแหบมากจนแทบจะไม่มีเสียง

4. ท่านมีอาการคลื่นไส้ที่กินเวลานานเกิน 10 นาทีหรือไม่

5. ท่านมีอาการอาเจียนหรือขย้อน หรือไม่

6. ท่านมีความพึงพอใจในระดับใดกับวิธีการใช้ท่อหายใจวิธีนี้

   0 = ไม่พอใจอย่างยิ่ง

   1 = ไม่ค่อยพอใจ

   2 = พอใจปานกลาง

   3 = พอใจมาก

   4 = พอใจมากที่สุด

APPENDIX 5

Postanesthetic Discharge Scoring System (PADSS)

Vital signs	
2	Within 20% of preoperative value
1	20%-40% of preoperative value
0	40% of preoperative value
Activity, mental status	
2	Oriented and steady gait
1	Oriented or steady gait
0	Neither
Pain, nausea, vomiting	
2	Minimal
1	Moderate
0	Severe
Surgical bleeding	
2	Minimal
1	Moderate
0	Severe
Intake and output	
2	PO fluids and voided
1	PO fluids or voided
0	Neither

APPENDIX 6

ใบยินยอมของผู้เข้าร่วมโครงการวิจัย (Consent Form)

ชื่อผู้ป่วย .....

โดยทั่วไปการส่องกล้องเพื่อวินิจฉัยทางนรีเวชจะกระทำภายใต้การให้ยาสลบโดยการใส่ท่อหายใจ ถือเป็นวิธีมาตรฐานสำหรับการทำหัตถการนี้ เนื่องจากทำให้เกิดความปลอดภัยแก่ผู้ป่วยในด้านการช่วยหายใจ, การป้องกันการสำลักอาหาร และกรดเข้าปอด, การควบคุมสัญญาณชีพต่าง ๆ นอกจากนั้นสภาวะที่ผู้ป่วยได้รับยาสลบจะทำให้การทำหัตถการได้สะดวก ได้ผลดียิ่งขึ้น และลดอัตราเสี่ยงต่อผลแทรกซ้อนจากการทำหัตถการ แต่การใส่ท่อหายใจชนิดที่ผ่านกล่องเสียงจะทำให้ผู้ป่วยจะมีอาการเจ็บคอจากการใส่ท่อหายใจ ค่อนข้างมากซึ่งพบว่ามีรายงานถึง 45 %

ในปี 1995 ท่อช่วยหายใจชนิดใหม่ คือ LMA ProSeal™ ได้ถูกนำมาใช้และเป็นที่ยอมรับทั่วโลกว่าสามารถใช้ช่วยเปิดทางเดินหายใจได้อย่างปลอดภัย ซึ่งคาดว่าจะนำมาใช้แทนท่อหายใจมาตรฐานได้อย่างปลอดภัย และมีอาการเจ็บคอลดลง เนื่องจากวางอยู่ในกล่องเสียง จึงขอเชิญชวนผู้ป่วยเข้าโครงการวิจัย เพื่อเปรียบเทียบอาการเจ็บคอและความไม่สบายในลำคอ หลังการใส่ท่อหายใจระหว่าง LMA ProSeal™ (PLMA) กับ Profile Soft-Seal Cuff™ (PSSC) ในผู้ป่วยนอกที่มารับการส่องกล้องทางหน้าท้อง เพื่อวินิจฉัยทางนรีเวชวิทยา ซึ่งทำการศึกษาโดย พ.ญ.เกศชาดา เอื้อไพโรจน์กิจ ภาควิชาวิสัญญีวิทยา คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัยผลจากการศึกษาครั้งนี้จะเป็นแนวทางในการเลือกใช้ท่อหายใจที่เหมาะสมสำหรับการส่องกล้องทางนรีเวชต่อไป

หากท่านเข้าร่วมโครงการวิจัยนี้ ท่านจะได้รับการให้ยาสลบและใส่ท่อหายใจวิธีใดวิธีหนึ่งโดยวิธีสุ่มระหว่าง LMA ProSeal™ กับ Profile Soft-Seal Cuff™ ซึ่งเป็นท่อหายใจมาตรฐานภายใต้การเฝ้าระวังการเต้นของหัวใจ, ความดันโลหิต, ภาวะออกซิเจน และคาร์บอนไดออกไซด์ในเลือด และผู้ป่วยจะเป็นผู้ประเมินอาการเจ็บคอและความไม่สบายในลำคอ จำนวน 2 ครั้ง คือ 2 ชม.ในห้องผ่าตัด และ 24 ชม.ที่บ้านทางโทรศัพท์ ข้อมูลที่ได้จากการศึกษาจะได้รับการรวบรวมอยู่ในฐานข้อมูลทางคอมพิวเตอร์ ข้อมูลดังกล่าวรวมทั้งการเผยแพร่ผลการศึกษาครั้งนี้จะไม่ระบุชื่อของท่าน

เนื่องจากการศึกษาครั้งนี้ได้รับทุนวิจัยจากคณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย จึงอาจมีการตรวจสอบความถูกต้องโดยคณะกรรมการพิจารณาทุนวิจัย ทั้งนี้จะกระทำได้ภายใต้ความยินยอมของท่าน

หากท่านเข้าร่วมโครงการนี้ ท่านจะไม่ต้องเสียค่าใช้จ่ายใด ๆ สำหรับการใช้ท่อหายใจที่เกี่ยวข้องกับการศึกษาครั้งนี้ รวมทั้งค่าใช้จ่ายอื่น ๆ อันเป็นผลแทรกซ้อนจากการศึกษา ถ้าท่านไม่

ยินดีเข้าร่วมโครงการวิจัยนี้ ท่านยังคงได้รับการดูแลตามปกติที่ควรได้รับจากโรงพยาบาลจุฬาลงกรณ์เช่นเดิม ท่านสามารถตัดสินใจเข้าร่วมโครงการหรือไม่ก็ได้โดยความสมัครใจ โดยจะไม่มีผลใด ๆ ต่อการดูแลรักษาพยาบาล

ข้าพเจ้าได้อ่านข้อมูลข้างต้น รวมทั้งได้รับการอธิบายจากคณะผู้ทำวิจัย และสมัครใจเข้าร่วมโครงการ

.....	.....	.....
ชื่อผู้ป่วยเข้าร่วมโครงการ	ชื่อแพทย์ผู้ทำวิจัย	ชื่อพยาน
.....	.....	.....
ลายเซ็น	ลายเซ็น	ลายเซ็น
.....	.....	.....
วันที่	วันที่	วันที่

แพทย์ผู้ทำวิจัย รศ.พ.ญ.เกศชาดา เอื้อไพโรจน์กิจ ภาควิชาวิสัญญีวิทยา
คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
โทร. 09-6644730

APPENDIX 7

Patient Information and Consent Form

We would like to ask you to participate in a research study to be conducted by Dr.Ketchada Uerpairojkit.

The study is being carried out to see if the severity of postoperative sore throat after LMA ProSeal™ (PLMA) is different from after Profile Soft-Seal Cuff ™ (PSSC) in ambulatory gynecologic laparoscopy.

Generally, patients undergoing ambulatory gynecologic laparoscopy in Chulalongkorn hospital would receive sedation to reduce patient's discomfort during this procedure. Because of the shortage of anesthesiologist, sedation has been used although this technique sometimes produces poor exposure and much of limitation for the intervention via a laparoscope.

The standard technique of anesthesia for the above mentioned procedure is general anesthesia with endotracheal tube. Besides the better condition for the procedure, this technique provides adequate oxygenation and ventilation without intraoperative feeling of pain. However, about 45 % of patients are suffered from sore throat after intubation. LMA ProSeal™ (PLMA) has been used since 1995 and reported for its effectiveness as an alternative airway device for laparoscopic surgery. It usually produces less sore throat and other throat discomfort. Therefore, it should be worth to imply this device for an ambulatory patient, who is suffered most from throat discomfort and disabilities for normal daily activity. This study will compare throat discomfort after PLMA and Profile Soft-Seal Cuff (PSSC) which is a new model of endotracheal tube. The result of this study will be an appropriate management for airway control in ambulatory gynecologic laparoscopy. If you participate in this study, you will receive general anesthesia via either one of these 2 airway techniques randomly and be monitored for blood pressure, oxygenation and ventilation during anesthesia. You will be blinded to these techniques and an assessor will ask you to give scores for throat discomfort, nausea symptom and satisfaction, at 2 and 24 hr postoperatively.

The Department of Anesthesiology would like to invite you to take part in this study. Your participation in the study is voluntary. You may refuse to take part or may decide to stop at any time. This will not affect your relationship with the doctor, who will give you the best treatment he can offer. Also, your doctor may decide that you should not participate in this study if appropriate. Then, sedation technique as a former practice will be provided if you do not wish to take part in the study.

The information collected during the study will be stored in a computer but your name will not be. Only your doctor will know that the information is related to you. The results of the study may be published in the medical literature, but your identity will not be revealed.

As this protocol will be granted by the faculty of medicine, Chulalongkorn University, authorized persons of the faculty may look at your medical records, without violating confidentiality, to check that the study has been properly performed. This can only be done with your permission, and it is therefore understood that by signing the Consent Form you are thereby granting this permission.

The cost of airway devices will be supported by the grant from the Faculty of Medicine, Chulalongkorn University. If you are caused any injury directly by your participation in the study, you will be under specialized care by the authorized staffs in the Faculty without extra-payment.

In case of a study-related injury, or whenever you have questions about the study, please contact Dr. Ketchada Uerpairojkit Tel. 09-6644730

I have read all of this protocol thoroughly and got all the needed information from the investigators.

I intentionally participate in this study.

…….	…….	…….
Subject's name	Investigator's name	Witness's name
…….	……..	……..
Signature	Signature	Signature
…….	…….	…….
D / M / Yr	D / M / Yr	D / M / Yr

APPENDIX 8

CASE RECORD FORM

Pat initials …… Pat No. |__|__|__|

Assessment date dd mm yy

Postoperative throat discomfort after using LMA-ProSeal™versus Profile Soft-Seal Cuff™ for general anesthesia under ambulatory gynecologic laparoscopy

Principal Investigator

Name : Dr.Ketchada Uerpairojkit

Address : Department of Anesthesiology
Chulalongkorn University Hospital
Bangkok, Thailand

Telephone : +662 256 4215
Fax : +662 256 4294

Pat initials ..... Pat No. .....

Assessment date .....
dd mm yy

Eligibility Criteria

Inclusion Criteria	**No**	**Yes**
Written informed consent	[ ]	[ ]
Age ≥ 18 yr.	[ ]	[ ]
ASA physical status I or II	[ ]	[ ]
Elective	[ ]	[ ]

Exclusion Criteria		
BMI > 35 kg/m^2	[ ]	[ ]
Throat discomfort	**0**	**≥ 1**
(Sore throat/dysphagia/dysphonia score ≥ 1)	[ ]	[ ]

If yes specify

	No	**Yes**
Risk of difficult mask ventilation	[ ]	[ ]

If yes specify

Risk of difficult intubation		
- Modified Mallampati class III or IV	[ ]	[ ]
- History of difficult intubation	[ ]	[ ]
- Thyromental distance < 4	[ ]	[ ]
- Interincisor gap < 2 cm	[ ]	[ ]
Risk of aspiration		
- Upper airway lesion, infection or pathology	[ ]	[ ]
- Cardiovascular, respiratory disease	[ ]	[ ]
- Bleeding disorder	[ ]	[ ]
- Cannot be contacted by telephone at 24 hr postop.	[ ]	[ ]

Conclusion

Patient fulfils all inclusion criteria and none of the exclusion criteria	[ ]	[ ]

Withdraw Patient _____/_____

Patient Description

date of birth .....Weight ..... Height.....
dd mm yy kg cm

No Yes
Any history of allergy [ ] [ ] If Yes, please specify.....

Physical Examination

Specification of Abnormalities	Normal	Abnormal
General appearance	[ ]	[ ]
Lymph nodes	[ ]	[ ]
Thyroid	[ ]	[ ]
Heart	[ ]	[ ]
Lung	[ ]	[ ]
Abdomen	[ ]	[ ]
Nervous system	[ ]	[ ]

Pulse (beats/min) ..... Blood Pressure (mmHg) .....

Medical History

Has patient any current or past major conditions other than the reason for the surgical procedure No [ ] Yes [ ]
If Yes please specify below

Past	Current	Current medication
[ ]	[ ]	.....
[ ]	[ ]	.....
[ ]	[ ]	.....

Surgical History

Has patient undergone any major surgery previously No [ ] Yes [ ] If Yes please specify .....
Current medication No[ ] Yes [ ] If Yes please specify .....

Pat initials ..... Pat No. .....

Assessment date .....
dd mm yy

Operative period

Surgical Diagnosis **Surgical Procedure**

....

Anesthetic start time Extubation time

....

Baseline characteristics 0 1 2

Intubation difficulty [ ] [ ] [ ]

0 = 1 attempt, no tactile resistance 1 = 1 attempt some tactile resistance 2 = ≥ 2 attempts

No Yes

Blood on device [ ] [ ]

Gastric decompression [ ] [ ]

3rd-time intubating failure [ ] [ ]

If Yes, the alternative airway device No [ ] Yes [ ] If Yes, that airway device is .....success No [ ] Yes [ ]

Ventilating failure [ ] [ ]

If Yes, that airway device is .....success No [ ] Yes [ ]

1st-time intubating success [ ] [ ]

Efficacy

Leak pressure of LMA [ ] cmH_2O

Ventilation status No Yes

FiO_2 > 0.33 [ ] [ ]

FGF > 3 l/min [ ] [ ]

MV > 10 x 12 [ ] [ ]

No. of time used of PLMA [ ]

2 hr postoperative peroid

0 1 2 3

Sore throat [ ] [ ] [ ] [ ]

0 = no pain, 1 = mild, 2 = moderate, 3 = severe

Dysphagia [ ] [ ] [ ] [ ]

0 = easily swallow 1 = some degree of difficulty, 2 = very difficult, 3 = cannot swallow

Dysphonia [ ] [ ] [ ] [ ]

0 = no voice change, 1 = minimal, 2 = apparently, 3 = no voice

No Yes

Nausea [ ] [ ]

Vomiting [ ] [ ]

Conscious level 0 1 2 3

[ ] [ ] [ ] [ ]

0 = does not respond 1 = asleep, responds to touch or pain2 = asleep, responds to verbal command 3 = fully awake, open eyes

VNS of pain 0 to 10 from none to the most severe [ ]

---

24 hr postoperative period

0 1 2 3

Sore throat [ ] [ ] [ ] [ ]

0 = no pain, 1 = mild, 2 = moderate, 3 = severe

Dysphagia [ ] [ ] [ ] [ ]

0 = easily swallow, 1 = some degree of difficulty, 2 = very difficult, 3 = cannot swallow

Dysphonia [ ] [ ] [ ] [ ]

0 = no voice change, 1 = minimal, 2 = apparently, 3 = no voice

No Yes

Nausea [ ] [ ]

Vomiting [ ] [ ]

VNS of pain 0 to 10 from none to the most severe [ ]

---

0 1 2 3 4

Satisfaction [ ] [ ] [ ] [ ] [ ]

0 = not satisfy at all, 1 = not satisfy, 2 = satisfy, 3 = very satisfy, 4 = most satisfy

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VITAE

Mrs. Ketchada Uerpairojkit was born on April 6th, 1964 in Bangkok, Thailand.

She graduated as Medical Doctor from the Faculty of Medicine, Siriraj Hospital, Mahidol University in 1988.

During 1988-1991, she attended residency program of Anesthesia at the Department of Anesthesia, Faculty of Medicine, Chulalongkorn University and was certificated in 1991 from Royal College of Anesthesiologists of Thailand.

In 1991, she started to work as an instructor in the Department of Anesthesia, Faculty of Medicine, Chulalongkorn University.

In 1993, she was certificated in Fellowship in Anesthesia, Japanese Council for Medical Training, Tokyo, Japan.

In 1995, she was a fellow in Department of Anesthesia, Indiana Medical Center, Indianapolis, Indiana, U.S.A.

At present, she is Associated Professor, Department of Anesthesia, Faculty of Medicine, Chulalongkorn University.