

Profile Soft-Seal Cuff™ for General Anesthesia under Ambulatory Gynecologic Laparoscopy

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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

Material and Method: One hundred and thirty eight patients undergoing ambulatory gynecologic laparoscopy in Chulalongkorn Memorial Hospital were randomly allocated into two groups. One group was 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 hours and 5-leveled satisfaction score to both techniques at 24 hours postoperatively were evaluated.

Results: The patients in the PLMA group had less severe symptoms of sore throat ($p = 0.016$) and dysphonia ($p = 0.003$) than those in the PSSC group at 2 hour. No difference was detected for dysphagia, nausea, vomiting, and satisfaction scores at 24 hour postoperatively.

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

Keywords: LMA-ProSeal, sore throat, dysphonia, dysphagia

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Postoperative throat discomfort has been identified as a problem that patients consider undesirable after ambulatory anesthesia⁽¹⁾. Sore throat, dysphagia, and hoarseness are the major complaints of the patients after endotracheal intubation (ETT). This disturbs patient's satisfaction, speech function, and quality of life after discharge. Moreover, these throat irritations may stimulate the cranial nerve of laryngopharynx and induce the higher incidence of postoperative nausea and vomiting (PONV)⁽²⁾.

Laryngeal mask airway (LMA) has been widely studied for its comparable effectiveness. Being a supraglottic device, LMA belongs to superior results on throat symptoms, compared to ETT⁽³⁻⁵⁾. Recently, the LMA-ProSeal™ (PLMA: the Laryngeal-Mask Company, Henley-on-Thames, UK) was invented, which permits higher airway pressure with less gas

leak and facilitates gastric or suction tube placement^(6,7). Many studies have confirmed its acceptable efficacy in higher airway pressure control for high intraperitoneal pressure during laparoscopy^(8,9).

Profile Soft-Seal Cuff™ endotracheal tube (PSSC: Sims Portex, Kent, UK) belongs a high compliance, N₂O-barrier cuff, and had been reported for its advantage of less sore throat^(10,11). However, there still had been no study that compared these postoperative throat symptoms after using these two devices. The authors therefore designed an RCT to compare postoperative sore throat, dysphagia, hoarseness, nausea and vomiting in an ambulatory anesthesia undergoing gynecologic laparoscopy at early (2-hour) and late (24-hour) postoperative periods.

Material and Method

After local institutional ethics committee approval and written consent, 138 female ASA physical status I-II outpatients aged > 18 years, scheduled for

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diagnostic gynecologic laparoscopy or laparoscopic tubal sterilization were recruited for the present study. Patients were not recruited if they had any of the following: a risk of difficult mask ventilation or difficult intubation (history of difficult intubation, modified mallampati class III or IV⁽¹²⁾, thyromental distance < 4 cm, interincisor gap < 2 cm), BMI > 35 kg/m², risk of aspiration (nonfasted, gastro-esophageal reflux), any symptoms of sore throat, dysphagia or hoarseness, upper airway lesion, cardiovascular or respiratory disease, bleeding disorder, cannot achieve a telephone interview at 24 hr postoperation, and patients refusal to participate in the present study.

The randomization for the different groups of the two airway techniques were done by a computerized generation program and was concealed to the patients and the outcome assessor. Only the anesthesiologist that opened the envelopes before an airway insertion was aware of the method.

The primary outcome was the difference in severity of sore throats between the two groups at the early postoperative periods. Sample size of 69 was calculated by using Wilcoxon Mann-Whitney rank sum test by N Query Advisor[®] Version 5.0^(13,14). This would detect the difference of the primary outcome, with 2-sided type I error of 5%, and power of 95%.

Without any premedication, the patient was in the lithotomy position with her head on a 7-cm standard pillow. Monitoring of blood pressure, oxygen saturation by pulse oximeter, and EKG were applied.

After obtaining baseline vital signs, fentanyl 1 mcg/kg i.v. was given. Three minutes later, an anesthesia was subsequently induced with propofol 2 mg/kg i.v. and atracurium 0.3 mg/kg i.v., and maintained with propofol 100-200 mcg/kg/min i.v. and FiO₂ 1.0 ventilatory via a facemask. Three minutes later, the allocated airway device, lubricated with a clear water-based gel was inserted. For the PLMA group, the digital technique for standard LMA insertion was performed during neck flexion, head extension and full deflation of the PLMA cuff⁽¹⁵⁾. However, lateral approach would be an alternative if major resistance was felt along the insertion path. Failed insertion was defined by either failed passage into the pharynx or ineffective ventilation, *i.e.* SpO₂ < 95% or P_{ET} CO₂ > 45 mmHg even with Fi O₂ 1.0 or 12ml/kg tidal volume (V_T) and 16/min respiratory rate (RR), then repositioning the device would be needed. In case of three failed intubations or insertions, then the other technique would be an alternative and the data were analyzed on an intention to treat basis. Cuff inflation to reach the cuff pressure

at 60 cmH₂O for PLMA and just sealed cuff inflation at 25 cmH₂O airway pressure for PSSC were performed⁽¹⁶⁾. Then the leak pressure of PLMA was determined by closing an adjustable pressure limit valve to achieve a plateau pressure at 3 l/min breathing flow. Then, all patients were under respiratory control with 3 l/min flow rate of 66% N₂O in O₂, 10 ml/kg tidal volume (V_T) and 12/min respiratory rate (RR). Any airway trauma and visible or occult blood was noted. Sore throat, hoarseness and dysphagia were assessed at 2- and 24-hour postoperatively.

Through the procedure, the anesthesiologist maintained with 66% N₂O and propofol. Then, all the anesthetic agents were withheld at the last stitch of the skin suture. The airway device was removed after the patients opened their eyes and resumed their handgrip strength. Any airway trauma and visible or occult blood was noted.

Sore throat, hoarseness and dysphagia, including nausea, vomiting, and abdominal pain were assessed by the same blinded assessor at 2- and 24-hour postoperatively after extubation. The patient would receive acetaminophen 1 g orally according to a request and was discharged after PADSS score above 9⁽¹⁷⁾. At 24-hour after the procedure, all of those scores including that of satisfaction were reassessed by telephone interview.

Demographic data were obtained, including weight, height, BMI, age, and the duration of anesthesia. Difficult PSSC intubation or PLMA insertion was graded by a 3-point scale; *i.e.*, 0 for 1 attempt with no tactile resistance, 1 for the some resistance, and 2 for > 1 attempt. If it was more than three times of the airway insertion, then it was classified as an intubating or insertion failure. As a result, the fourth intubation was crossed over to the other technique. For the assessment of throat discomforts, four-point scale was used as follows, sore throat: 0-no pain, 1-mild, 2-moderate, 3-severe; dysphagia: 0-easily swallowing, 1-some degree of difficulty, 2-very difficult, 3-cannot swallow; hoarseness: 0-no voice change, 1-minimal, 2-apparently, 3-no voice could be expressed. Similarly, a 5-point scale for patient satisfaction to the airway technique was used (Score 0-not satisfy at all, 1-not satisfied, 2-satisfy, 3-very satisfy, 4- most satisfy). Finally, a verbal numeric score (VNS 0-10) was used for surgical pain. The present symptom of nausea or vomiting was recorded as binary outcomes.

Statistical analysis was performed by SPSS program version 11.0. The data were expressed as frequency and percentage, mean with standard

deviation (SD) or median and inter-quartile range as appropriate. Chi-squared test for trend for the grading outcomes and Chi-squared test for the dichotomous outcomes were used. Fisher's exact test was an alternative for very small expected frequencies. Statistical significant was set at $p < 0.05$.

Results

One hundred and thirty eight patients were included in the present study. Demographic data is as shown (Table 1) and is completed except for one patient in the PSSC group who could not be contacted by phone.

Table 1. Patients' characteristics, operative time and types of operation

Airway	PSSC (n = 69)	PLMA (n = 69)
Age (yrs)	34.3 (4.1)	34.6 (3.8)
Weight (kg)	54.4 (8.2)	52.8 (7.9)
Height (cm)	156.4 (5.3)	156.9 (5.2)
BMI (kg/m ²)	22.2 (3.0)	21.5 (3.3)
Operative Time (min)	32.0 (12.0)	30.2 (8.6)
Procedure* LDx/LTR	63/6 (91.3/8.7%)	66/3 (95.7/4.4%)

Values are mean (SD) or number (percentage)

LDx: diagnostic laparoscopy; LTR: laparoscopic tubal resection

Table 2. Difficulties and success rate of airway insertion

	Scales of difficult airway insertion			Bloody stain on device	Gastric decompression	3 rd failed attempt of airway insertion	1 st successful attempt of airway insertion
	0	1	2				
PSSC (n = 69)	55 (79.7%)	12 (17.4%)	2 (2.9%)	2 (2.9%)	0	1 (1.4%)	67 (97.1%)
PLMA (n = 69)	54 (78.3%)	12 (17.4%)	3 (4.3%)	5 (7.2%)	5 (7.2%)	0	68 (98.6%)

Values are expressed as frequencies, percentages, median (interquartile range)

Table 3. Throat discomforts 2 h and 24 h postoperatively

	Sore throat				Dysphagia				Hoarseness			
	0	1	2	3	0	1	2	3	0	1	2	3
2 h												
PSSC (n = 69)	32 46.4%	31 44.9%	6 8.7%	0	31 44.9%	35 50.7%	3 4.3%	0	8 11.6%	53 76.8%	8 11.6%	0
PLMA*+ (n = 69)	46 66.7%	21 30.4%	2 2.9%	0	39 56.5%	29 42.0%	1 1.4%	0	23 33.3%	42 60.9%	4 5.8%	0
24 h												
PSSC (n = 68)	51 75.0%	15 22.1%	1 1.5%	1 1.5%	56 82.4%	10 14.7%	1 1.5%	1 1.5%	49 72.1%	18 26.5%	1 1.5%	0
PLMA (n = 69)	52 75.4%	16 23.2%	1 1.4%	0	57 82.6%	12 17.4%	0	0	58 84.1%	11 15.9%	0	0

Value are expressed as frequencies, percentages

* $p = 0.016$, comparing of sore throat between PLMA and PSSC

+ $p = 0.003$, comparing of hoarseness between PLMA and PSSC

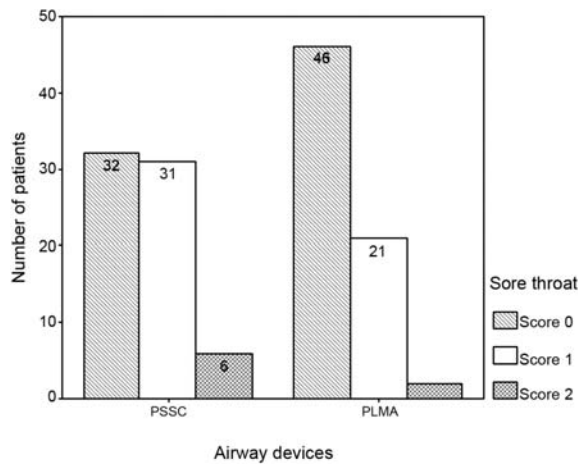


Fig. 1 Number of patients suffering from sore throat after PSSC and PLMA ($p = 0.016$)

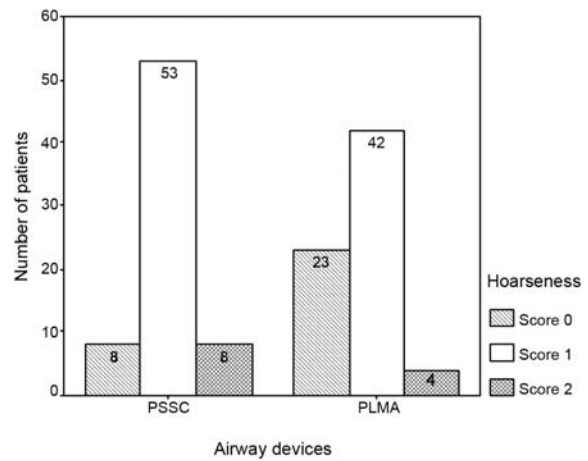


Fig. 2 Number of patients suffering from hoarseness after PSSC and PLMA ($p = 0.003$)

The first insertion success was found in almost all, except one patient in PLMA and two patients in the PSSC groups. One of the PSSC intubation failed after three attempts and was successfully done using the PLMA method. The patients that received nasogastric tube insertion were all in the PLMA group. In the two groups, insertion difficulties and proportion of airway trauma were not different (Table 2).

Chi-squared test for trend revealed higher of both postoperative sore throat ($p = 0.016$) and hoarseness ($p = 0.003$) at the 2-hour but not 24-hour postoperatively (Table 3) (Fig. 1, 2). Compared to PLMA, PSSC had a higher risk of sore throat (relative risk (RR) 1.609 with 95% CI 1.079 and 2.398) and hoarseness (RR 1.326 with 95% CI 1.099 and 1.599). Additionally,

binary logistic regression analysis revealed that PSSC intubation and the difficulty of airway insertion are the two explanatory factors for sore throat.

However, the statistical significance was not found for dysphagia, nausea, vomiting and satisfaction to the airway device (Table 4). The statistical significance showed a higher incidence of nausea among the patients suffering from a sore throat ($p = 0.018$) (Fig. 3), and lower score of satisfaction in patients with a sore throat ($p = 0.035$) (Fig. 4) and hoarseness ($p = 0.034$) (Fig. 5).

About the cost minimization, the cost of disposable PCSS was 117.70 Baht (3.46 USD when 34 Baht = 1 USD). For PLMA, the maximum cost per use was 275.38 Baht (8.10 USD), when the cost of one

Table 4. Nausea, vomiting, and satisfaction at 2 and 24 h postoperatively

	Nausea		Vomit		Satisfaction PSSC (n = 68), PLMA (n = 69)				
	2h	24h	2h	24h	0	1	2	3	4
PSSC	16 23.19% n = 69	3 4.4% n = 68	4 5.80% n = 69	0 n = 68	0	0	7 10.3%	29 42.6%	32 47.1%
PLMA	18 26.09% n = 69	6 8.7% n = 69	0 n = 69	1 1.4% n = 69	0	0	3 4.3%	30 43.5%	36 52.2%

Value are expressed as frequencies, percentages

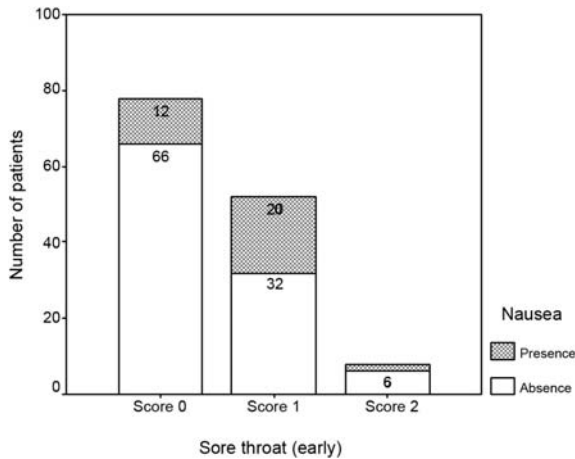


Fig. 3 Association of nausea and sore throat ($p = 0.018$)

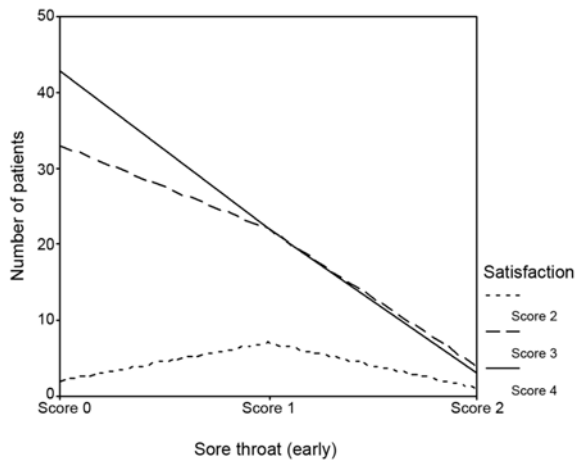


Fig. 4 Association of satisfaction and sore throat ($p = 0.035$)

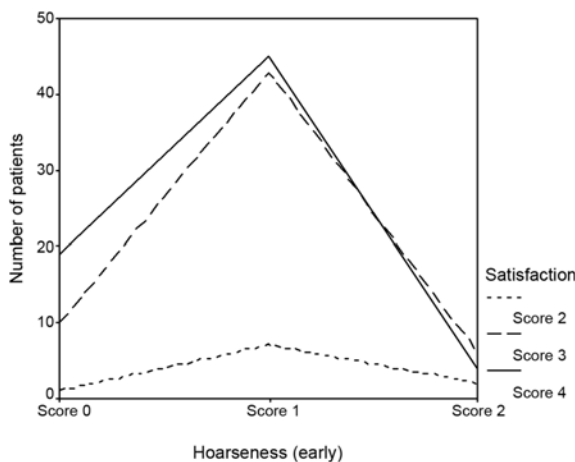


Fig. 5 Association of satisfaction and hoarseness ($p = 0.034$)

out of 40 times guaranteed use (10,800/40 Baht, 317.65/40 USD) was added up with the cost of disinfection process (5.38 Baht, 0.16 USD/use).

Discussion

Irritation of the subglottic structures by endotracheal tube usually results in a sore throat and hoarseness. Compared to PLMA, PSSC resulted in higher incidence of sore throat (53.6% vs. 33.3%, RR 1.6) and hoarseness (87.9% vs. 66.7%, RR 1.3). However, the incidence for dysphagia was comparable between the groups.

The higher incidence of sore throat and hoarseness may be caused by many factors, such as airway techniques, anesthetic skills, or higher cuff pressure needed during intraperitoneal gas insufflations. According to the present study, sore throat and hoarseness were associated with more difficult and forceful insertion of the airway device. Therefore, the authors should consider the anatomical variation and choose the most appropriate technique for each individual.

The limited cuff pressure of PLMA at 60 cmH₂O might have little effect on the muscle groups of swallowing. Types of the airway devices and the tactile resistance during airway insertion were shown to have a direct influence on sore throat and hoarseness, but were not on dysphagia.

For the incidence of nausea and vomiting, the present study supports the result of the former one that sore throat increased the incidence of nausea. Laryngeal stimulation might transmit the impulse via the cranial nerve and aggravated nauseated feeling. Notably, none of these patients gave a score reflecting unsatisfaction (score 0 or 1). This reflects that these patients might not be disturbed by those modest throat symptoms. Patient's assessment about her daily functional disturbance of speech, drinking, or eating might be more distinguishable. However, the patients were more satisfied with less severe throat symptoms.

Considering the efficacy and safety, the present study supports the previous ones that PLMA can be an alternative device for mechanical ventilation in gynecological laparoscopy^(8,9,18). Therefore, PLMA should be an alternative one in the difficult airway algorithm. According to the present study, the 60 cmH₂O cuff pressure of PLMA was enough for ventilation control in all our patients, who were lean females (BMI 22.20 ± 2.99 kg/m², maximum of 33.3 kg/m²). Natali et al recommended its safe use in those with BMI under 35 kg/m²(14). More air leak is a probable

problem in the obese groups, for which further studies are required. Since the efficacies of these two airway devices were comparable, the authors performed cost minimization for economic analysis. The cost of PLMA is more expensive than PSSC unless it was used more than 96 times. Using PLMA needs an additional 157.68 Bht (4.64 USD) compared to PSSC for each of the first 40-uses of PLMA. After the 40th use, an additional cost would be $10,800/n + 5.38 - 117.70 \text{ Baht}$ ($317.65/n + 0.16 - 3.46 \text{ USD}$), when n is the number of times the PLMA is used. However, some other intangible costs and benefits have not been calculated. One patient with intubation failure was safely inserted with PLMA, so that the possible risks of airway problems had been avoided.

However, to select the appropriate airway device, patient's safety and cost-effectiveness should all be considered. The groups of the present study were 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 the present 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 causes lower incidence and severity of both sore throat and hoarseness, but does not reduce dysphagia in the early postoperative period. However, it did not influence the outcomes of dysphagia, nausea, vomiting, and satisfaction. Its efficacy and safety were comparable to PSSC and it can be used as an alternative airway technique for general anesthesia in ambulatory gynecologic procedures based on economical consideration.

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อาการไม่สบายในคอหลังการใส่ท่อหายใจระหว่าง LMA-ProSeal™ กับ Profile Soft-Seal Cuff™ ในผู้ป่วยที่มารับการส่องกล้องทางนรีเวช

เกศชาดา เอื้อไพโรจน์กิจ, สมรัตน์ จารุลักษณะนันท์, เทวรักษ์ วีระวัฒนกานนท์, ธิระศักดิ์ พุ่มสีทอง

วัตถุประสงค์: เพื่อเปรียบเทียบความรุนแรงของอาการไม่สบายในลำคอ ได้แก่ อาการเจ็บคอ, กลืนลำบาก และเสียงแหบ ระหว่าง LMA-ProSeal (PLMA) กับ Profile Soft-Seal Cuff (PSSC) ในระยะแรก (2 ชั่วโมง) และระยะหลัง (24 ชั่วโมง) หลังผ่าตัดส่องกล้องทางนรีเวชแบบผู้ป่วยนอก

รูปแบบการศึกษา: การศึกษาเชิงทดลองทางคลินิกแบบสุ่มตัวอย่าง

สถานที่ทำการศึกษา: โรงพยาบาลจุฬาลงกรณ์เฉลิมพระเกียรติ ซึ่งเป็นโรงพยาบาลระดับตติยภูมิ

วัสดุและวิธีการ: ผู้ป่วย 138 รายที่มารับการส่องกล้องทางนรีเวชแบบเข้าไปเย็นกลับ จะได้รับการจัดเป็น 2 กลุ่มโดยวิธีสุ่มคือ กลุ่มหนึ่งได้รับการใส่ท่อหายใจด้วย PSSC และอีกกลุ่มหนึ่งด้วย PLMA 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 จึงเป็นอีกทางเลือกหนึ่งของการใส่ท่อหายใจสำหรับการดมยาสลบในการส่องกล้องทางหน้าท้องในผู้ป่วยนอกทางนรีเวช