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A study of airway management using the ProSeal LMA® laryngeal mask airway compared with the tracheal tube on postoperative analgesia requirements following gynaecological laparoscopic surgery

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Summary

In a randomised double blind prospective study, we tested the hypothesis that postoperative pain is lower in patients who receive an ProSeal LMA™ laryngeal mask airway compared with a tracheal tube. One hundred consecutive female patients (ASA I–II, 18–75 years) undergoing laparoscopic gynaecological surgery were divided into two equal-sized groups for airway management with the ProSeal LMA or tracheal tube. Anaesthesia management was identical for both groups and included induction of anaesthesia using propofol/fentanyl, and maintenance with propofol/remifentanil, muscle relaxation with rocuronium, positive pressure ventilation, gastric tube insertion, dexamethasone/tropisetron for anti-emetic prophylaxis, and diclofenac for pain prophylaxis. All types of postoperative pain were treated using intravenous patient-controlled analgesia (PCA) morphine. Patients and postoperative staff were unaware of the airway device used. Data were collected by a single blinded observer. We found that pain scores were lower for the ProSeal LMA at 2 h and 6 h but not at 24 h. Morphine requirements were lower for the ProSeal LMA by 30.4%, 30.6% and 23.3% at 2, 6 and 24 h, respectively. Nausea was less common with the ProSeal LMA than with the tracheal tube at 2 h and 6 h but not at 24 h. There were no differences in the frequency of vomiting, sore throat, dysphonia or dysphagia. We conclude that postoperative pain is lower for the ProSeal LMA than the tracheal tube in females undergoing gynaecological laparoscopic surgery.

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Postoperative pain is of paramount importance to patients and much of the clinical workload of the anaesthetist is directed towards reducing pain using drugs acting on various parts of the pain pathway. Pre-emptive analgesia is the concept that a reduction in central sensitisation prior to surgery will lead to a reduction in pain following surgery [1]. There is evidence that analgesic requirements and pain scores are lower with spinal than with general anaesthesia 6–24 h following surgery [2]. In principle, the choice of airway device may influence postoperative pain as some are less stimulating than others, as evidenced by variations in haemodynamic and reflex airway responses [3]. There is some early tentative evidence that extraglottic airways compared with subglottic airway devices are associated with a reduced requirement for analgesia postoperatively [4–6]; however, in none of these studies was pain the primary variable. The ProSeal laryngeal mask airway (ProSeal LMA™; Laryngeal Mask Company, Henley-on-Thames, UK) is a relatively new extraglottic airway device with a modified cuff to increase the seal and a drain tube to provide a channel for regurgitated fluid, prevention of gastric insufflation and insertion of a gastric tube [7, 8]. In a randomised double blind prospective study, we tested the hypothesis that postoperative pain is lower with the ProSeal LMA than with the tracheal tube.

Methods

One hundred consecutive female patients (American Society of Anesthesiologists grade I–II, 18–75 years) undergoing elective gynaecological laparoscopic surgery (diagnostic, uni- and bilateral ovarian resection, ovarian cyst resection, endometriosis resection, fibroidectomy) in the lithotomy position were studied. Ethical committee approval and written, informed consent were obtained. Patients were not considered for the trial if they had:

- a known or predicted difficult airway;
- oropharyngeal pathology;
- mouth opening < 3.0 cm;
- a body mass index > 35 $kg.m^{-2}$;
- chronic pain;
- allergy to any drugs used in the study protocol;
- an increased risk of aspiration;
- an inability to communicate or understand the visual analogue scale (VAS) or the patient-controlled analgesia device;
- received analgesics within 24 h of surgery.

Patients were randomly allocated into two equal-sized groups: airway management in one group, was with a tracheal tube, and in the other, with a ProSeal LMA. Randomisation was achieved using computer-generated numbers and allocation by opening a sealed opaque envelope immediately prior to surgery. Airway management was performed by one of the investigators (CK) and anaesthesia maintenance by anaesthetists with 3–5 years training under the direct supervision of CK. Surgery was performed by three fellowship-trained laparoscopic surgeons.

All patients were premedicated using midazolam 0.05–0.1 $mg.kg^{-1}$ orally 1 h pre-operatively. A standard anaesthesia protocol was followed and routine monitoring was applied. The patients' head rested on a pillow 7 cm in height. Induction of anaesthesia was with fentanyl 1–4 $\mu g.kg^{-1}$ and propofol 2.5–3.0 mg kg^{-1}. Maintenance of anaesthesia was with remifentanil 0.25–0.5 $\mu g.kg^{-1}min^{-1}$ and propofol 75–125 $\mu g.kg^{-1}min^{-1}$ in oxygen 33% and air. Prophylactic anti-emetics (intravenous dexamethasone 4 mg and tropisetron 2 mg) were administered to all patients following induction of anaesthesia. Neuromuscular blockade was produced using rocuronium 0.6 $mg.kg^{-1}$. Patients were ventilated using a face mask for 3 min until the train-of-four ratio was zero. The airway devices (size ID 7.0 mm for tracheal tube (Mallinckrodt Medical, Athlone, Ireland) and size 4 for ProSeal LMA) were used in strict accordance with their respective manufacturer's recommendations. Tracheal intubation involved obtaining the best possible view of the vocal cords using a Macintosh laryngoscope blade, and inserting the tracheal tube through the vocal cords into the trachea. ProSeal LMA insertion involved obtaining the best possible view of the hypopharynx using a Macintosh laryngoscope blade, inserting a gum elastic bougie with its straight end first through the hypopharynx into the proximal 5 cm of the oesophagus, and railroading the ProSeal LMA along its drain tube into the pharynx [9]. A maximum of two attempts were allowed to obtain an effective airway. A failed attempt was defined as removal of the device from the mouth. An effective airway was defined as two consecutive breaths with an expired tidal volume ≥ 6 $ml.kg^{-1}$. Insertion was considered to have failed if an effective airway was not obtained following two attempts. Both devices were fixed by taping the tube in the midline over the chin.

Once an effective airway was obtained, the intracuff pressure was set and held constant at 20 cm H_2O for the tracheal tube and 60 cm H_2O for the ProSeal LMA using a digital manometer (Mallinckrodt Medical). A well-lubricated 60-cm long (14FG) orogastric tube was inserted using laryngoscope-guidance in the tracheal tube group just prior to tracheal intubation and using the drain tube in the ProSeal LMA group. A maximum of two attempts were allowed. Correct gastric tube placement was assessed by suction of fluid or detection of injected air by epigastric stethoscopy [10]. A clear, water-based jelly (K-Y Lubricating Jelly, Johnson and Johnson, Maidenhead, UK) was used to lubricate the airway devices and gastric tubes. The gastric tube was suctioned following insertion and prior to removal and was left on free drainage at other times.

During the maintenance phase, patients' lungs were ventilated using pressure-controlled ventilation (Draeger Julian, Draeger, Lubeck, Germany) with peak airway pressure set at 15 cmH_2O, PEEP set at 5 cmH_2O, respiratory rate of 12 $breaths.min^{-1}$, inspiratory flow rate of 50 $l.min^{-1}$ and fresh gas flow of 1.5 $l.min^{-1}$. During pneumoperitoneum, peak airway pressures were increased to maintain E_TCO_2 at 5 kPa. Ringer's Lactate solution was administered at a rate of 10–15 $ml.kg^{-1}.h^{-1}$. Blood loss was replaced with Hetastarch at a 1 : 1 ratio to maintain normal intravascular volume. Diclofenac 75 mg was given intravenously during surgery and 12 h post-operatively. Forced air warming system was used to keep rectal temperature near 37 °C.

For the laparoscopic technique pneumoperitoneum was achieved using a 11-mm Versaport trocar (Tyco Healthcare, Norwalk, CT) inserted through a small infra-umbilical incision, and was maintained with carbon dioxide adjusted to a pressure of 14 mmHg. Two additional 5-mm trocars were placed under direct laparoscopic vision.

Muscle relaxation was reversed at the conclusion of surgery using neostigmine 1–2.5 mg and atropine

0.5–1.0 mg if the train-of-four ratio was < 0.8. The tracheal tube, ProSeal LMA and gastric tube were removed when the patient was spontaneously breathing and able to open their mouth to command. Any blood staining on the laryngoscope, tracheal tube or ProSeal LMA was documented. The total residual gastric volume was recorded. Anaesthesia time was from preoxygenation to removal of the airway device. Surgical time was from incision to insertion of the last suture. Cardiorespiratory data were collected every 5 min. Any episodes of bradycardia (< 40 min^{-1}), tachycardia (> 100 min^{-1}) or systolic hypotension (< 80 mmHg) were documented. Any episodes of hypoxia ($S_pO_2 < 90\%$) were documented.

In the post anaesthesia care unit, all types of postoperative pain were treated using intravenous morphine administered via a patient-controlled analgesia device (Graseby 3300, Smiths Medical, Brunn am Gebirge, Austria). The device was initiated in the immediate recovery period and continued for up to 24 h following surgery. The bolus dose was 1.5 mg intravenously, with a 10-min lockout interval, and a maximum 4 h dose of 30 mg. In the post anaesthesia care unit, nausea (on a visual analogue scale > 3 (VAS 0–10, where 0 is no nausea and 10 unbearable nausea) and vomiting (yes or no) was treated using droperidol 0.625 mg intravenously. Patients were discharged from the post anaesthesia care unit when they were awake, haemodynamically stable and when the S_pO_2 was $> 95\%$ on air.

Patients and postoperative staff were unaware of the type of airway device used. A single trained observer, who was blind to the airway device used, documented any adverse events at 2, 6 and 24 h following surgery. At the interview, patients were asked if they had any of the following symptoms: pain on a visual analogue scale at rest (VAS 0–10, where 0 is no pain and 10 unbearable pain), nausea on a visual analogue scale > 3 at any time since last interview, vomiting (yes or no at any time since last interview), sore throat (constant pain, independent of swallowing), dysphonia (difficulty speaking and pain on

Table 1 Demographic, surgical, anaesthetic and post anaesthesia care unit characteristics for both groups. Data are mean (SD) (number of patients) or numbers.

	Tracheal tube	ProSeal LMA	p value
n	50	50	
Age; year	37.2 (10.2)	38.4 (9.9)	NS
Height; cm	166.4 (5.7)	166.2 (6.2)	NS
Weight; kg	66.5 (11.2)	65.5 (12.7)	NS
BMI; kg.m^{-2}	24.1 (4.1)	23.7 (4.3)	NS
ASA I/II; *n*	45/5	45/5	NS
Laparoscopic procedures; *n*			
diagnostic	6	8	NS
ovarian cyst resection	16	18	NS
uni- and bilateral ovarian resection	13	11	NS
endometriosis resection	4	4	NS
fibroidectomy	11	9	NS
Anaesthesia induction and maintenance drugs			
Propofol; mg	194.2 (23.7) (50)	189.6 (24.2) (50)	NS
Fentanyl; mg	0.18 (0.04) (50)	0.17 (0.06) (50)	NS
Cumulative remifentanil; μg	1161 (608) (50)	1083 (400) (50)	NS
Cumulative propofol; mg	508 (293) (50)	471 (176) (50)	NS
Cumulative intra-operative crystalloids; ml	1110 (368) (50)	1080 (325) (50)	NS
Cumulative intra-operative colloids; ml	0	0	NS
Anaesthesia time; min	82 (37)	81 (26)	NS
Surgical time; min	55 (36)	54 (24)	NS
Insertion attempt; *n*			
First	50	50	NS
Second	0	0	NS
Blood detected on laryngoscope; *n*	1	0	NS
Blood detected on TT or PLMA; *n*	1	0	NS
Heart rate; beats.min^{-1}	66 (8)	66 (8)	NS
Heart rate < 40 or > 100 beats.min^{-1}; *n*	0	0	NS
Systolic blood pressure; mmHg	106 (8)	105 (9)	NS
Systolic blood pressure < 80 mmHg; *n*	1	1	NS
S_pO_2; %	98.1 (0.8)	98.2 (0.8)	NS
$S_pO_2 < 90\%$; *n*	0	0	NS
Total residual gastric volume; ml	16.2 (18.1)	18.7 (15.5)	NS
Post anaesthesia care unit time; min	92 (29)	91 (26)	NS
Post anaesthesia care unit droperidol*; mg	0.625 (0) (10)	0.625 (0) (2)	NS

*Mean (SD) based only on those given the drug.
BMI, body mass index; TT, tracheal tube; PLMA, ProSeal LMA.

speaking) and dysphagia (difficulty or pain provoked by swallowing). Patients were also asked the main location of any pain (abdomen, shoulder, incision, airway, others).

Sample size was based upon a projected difference of 33% between the groups for morphine consumption, a type I error of 0.05 and a power of 0.90, and was based on a pilot study with 10 patients. If the randomised device failed and the alternative device succeeded, all variables were assigned to the initial randomised device (intention to treat). The distribution of data was determined using Kolmogorov-Smirnov analysis [11]. Statistical analysis was with paired *t*-test or Fisher's Exact test. Outcome analysis was with ANOVA for repeated measurements. In the case of significant difference, further comparisons were made with paired *t*-test or Fisher's Exact test between groups at individual time points. The Bonferroni-Holm procedure was used for corrections of multiple comparisons. Significance was taken as $p < 0.05$.

Results

There were no important differences in demographic, surgical, anaesthetic or post anaesthesia care unit data (Table 1). Outcome data are presented in Table 2. Pain scores were lower for the ProSeal LMA at 2 h and 6 h but not at 24 h. Morphine requirements were lower for the ProSeal LMA by 30.4%, 30.6% and 23.3% at 2, 6 and 24 h, respectively. Nausea was less common with the ProSeal LMA than with the tracheal tube at 2 h and 6 h but not at 24 h. There were no differences in the frequency of vomiting, sore throat, dysphonia or dysphagia. The main location for pain was the abdomen at 2 and 6 h and the shoulder at 24 h ($p < 0.0001$). In no patient was the airway the main location for pain. Pain scores, morphine requirements and the frequency of nausea were also lower for the ProSeal LMA in the subpopulation with no airway morbidity (Table 3).

Discussion

We found that postoperative pain was lower with the ProSeal LMA than with the tracheal tube. This confirms the tentative findings from our previous study of 200 females undergoing a mixture of breast or gynaecological surgery in which the primary variable was postoperative nausea and vomiting [6]. Two other groups have shown that postoperative analgesic requirements are lower

Table 2 Outcome data. Data are mean (SD) or numbers.

	Time, h			p value	
	2 h	6 h	24 h	Time effect	Group effect
PCA morphine; mg				< 0.0001	0.006
Tracheal tube	7.9 (3.9)	13.4 (7.0)	16.7 (8.8)		
ProSeal LMA	5.5 (3.5)*§	9.3 (6.2)*§	12.8 (7.9)*		
Pain VAS at rest; cm				< 0.0001	0.038
Tracheal tube	4.0 (1.5	3.0 (1.4)	1.5 (1.0)		
ProSeal LMA	3.3 (1.2)*	2.4 (1.2)*	1.4 (0.9)		
Nausea (VAS > 3); *n*				–	0.027
Tracheal tube	10	8	1		
ProSeal LMA	2*	1*	0		
Vomiting; *n*				–	NS
Tracheal tube	6	4	0		
ProSeal LMA	1	1	0		
Sore throat; *n*				–	NS
Tracheal tube	4	4	2		
ProSeal LMA	2	1	1		
Dysphonia; *n*				–	NS
Tracheal tube	0	0	0		
ProSeal LMA	0	0	0		
Dysphagia; *n*				–	NS
Tracheal tube	1	1	0		
ProSeal LMA	0	0	0		
Location of main pain (abdomen/incision/shoulder/airway/others); *n*					
Tracheal tube	50/0/0/0/0	48/2/0/0/0	16/0/34/0/0	–	NS
ProSeal LMA	49/1/0/0/0	49/1/0/0/0	14/0/36/0/0		

*Significantly different by uncorrected post hoc group comparison ($p < 0.05$); §significantly different by Bonferroni-Holm-corrected post hoc group comparison ($p < 0.016$).

Table 3 Outcome data from patients without airway morbidity†. Data are mean (SD) or numbers

	Time, h			p value	
	2 h	6 h	24 h	Time effect	Group effect
PCA Morphine; mg				< 0.0001	0.008
Tracheal tube	7.9 (3.8)	13.4 (7.0)	16.9 (8.7)		
ProSeal LMA	5.5 (3.4)*§	9.4 (6.4)*§	12.8 (8.0)*		
Pain VAS at rest; cm				< 0.0001	0.032
Tracheal tube	4.0 (1.6)	3.0 (1.4)	1.5 (1.0)		
ProSeal LMA	3.3 (1.2)*§	2.3 (1.2)*	1.4 (0.9)		
Nausea (VAS > 3); *n*				–	0.014
Tracheal tube	10	8	1		
ProSeal LMA	2*§	1*§	0		
Vomiting; *n*				–	NS
Tracheal tube	6	4	0		
ProSeal LMA	1	1	0		

†No sore throat, dysphonia or dysphagia. $n = 46$ for tracheal tube; $n = 48$ for ProSeal LMA. *Significantly different by uncorrected post hoc group comparison ($p < 0.05$); §significantly different by Bonferroni-Holm-corrected post hoc group comparison ($p < 0.016$).

for laryngeal mask devices than the tracheal tube [4, 5]: Cork et al. [4], in a study of 44 patients for peripheral orthopaedic surgery; and Buniatian & Dolbneva [5] in a study of 146 patients for laparoscopic cholecystectomy. The current study also showed that nausea was less frequent with the ProSeal LMA, confirming our previous findings [6].

The combined findings of these studies suggest that laryngeal mask devices are associated with lower pain scores than is the tracheal tube. The presence of a cuff in the pharynx is much less stimulating than a cuff in the trachea [3]. We postulate that the pain centres are stimulated to a lesser extent by extraglottic than by subglottic airway devices during surgery, resulting in higher pain thresholds after surgery. The mechanism is perhaps similar to the pre-emptive analgesic effect occurring at the spinal level during spinal anaesthesia [1]. An alternative explanation is that analgesic requirements were lower with the ProSeal LMA as there was a trend for lower airway morbidity; however, analysis of the subpopulation with no airway morbidity yielded the same findings. Also, the main location of pain was always the abdomen (early) or shoulder tip (late) and never the airway. Our previous study also showed that the reduction in postoperative pain was unrelated to airway morbidity [6].

Our study has two limitations. Firstly, our data may not apply to other patient populations undergoing other surgical procedures. However, as other studies have detected a pre-emptive analgesic effect in orthopaedic surgery [4], laparoscopic cholecystectomy [5] and breast surgery [6], as well as gynaecological laparoscopy [6], it is likely that our findings are widely applicable. Secondly, the ProSeal LMA was inserted by an experienced anaesthetist using a guided technique, which has a very high first attempt insertion success rate, and our data may not apply to the less successful digital and introducer tool insertion techniques or with less experienced anaesthetists [9].

We conclude that postoperative pain is lower for the ProSeal LMA compared with a tracheal tube in females undergoing gynaecological laparoscopic surgery.

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