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ORIGINAL ARTICLE

Self-positioning followed by induction of anaesthesia and insertion of a laryngeal mask airway versus endotracheal intubation and subsequent positioning for spinal surgery in the prone position

A randomised clinical trial

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BACKGROUND Anaesthesia followed by positioning in the prone position takes time and may have complications.

OBJECTIVE The hypothesis was that self-positioning in the prone position followed by anaesthesia and introduction of a laryngeal mask airway (LM method) would be faster with fewer complications than positioning after tracheal intubation (ET method).

DESIGN Randomised, controlled trial.

SETTING University Hospital, March 2009 to March 2011.

PATIENTS One hundred forty patients scheduled for spinal surgery were allocated to the LM or the ET method. Exclusion criteria were surgery expected to last more than 2 h, American Society of Anesthesiologists status more than II, age more than 70 years, abnormal neck, throat, and mouth anatomy and function, Mallampati score III–IV, BMI more than 35 kg m^{-2}, anticipated difficult airway/mask ventilation and decreased neck mobility.

INTERVENTIONS Patients in the LM group placed themselves in the prone position, anaesthesia was induced and a laryngeal mask was introduced. Patients in the ET group were anaesthetised, intubated and then placed in the prone position.

MAIN OUTCOME MEASURES Time taken from identification of the patient at the outset to readiness for radiographic examination following anaesthesia and positioning. Airway problems, sore throat, hoarseness and pain from muscles and joints were also noted.

RESULTS One hundred and forty patients were randomised to LM ($n = 70$) and ET ($n = 70$). Data from 64 and 67 patients were analysed. Values are expressed as median (interquartiles) [range]. The primary outcome time was 25 min (23 to 29) [16 to 44] in the LM group and 30 min (26 to 33) [17 to 47] in the ET group ($P < 0.001$). In two patients in group LM, a complete seal could not be obtained; one was intubated, and the other had surgery cancelled due to arterial hypotension. There were fewer cases with sore throat, hoarseness and pain from muscles and joints in the LM group at 3 h, but not at 24 h postoperatively.

CONCLUSION Self-positioning and induction of anaesthesia in the prone position saves time. More patients should be studied to confirm safety and examine whether the method reduces the number of severe complications associated with the prone position.

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- Kranke P. Penny wise, pound foolish? Trade-offs when using the laryngeal mask airway for spine surgery in the prone position. *Eur J Anaesthesiol* 2014; **31:**249–252.
- Hinkelbein J. PRO: laryngeal masks can be used for surgery in the prone position. *Eur J Anaesthesiol* 2014; **31**:253–255.
- Staender S. CON: laryngeal masks must not be used for surgery in the prone position. *Eur J Anaesthesiol* 2014; **31**:256–258.

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Introduction

Insertion of a laryngeal mask airway in an anaesthetised patient placed in the prone position (LM method) has been described as an emergency procedure to obtain airway control.[1] Some studies have assessed the laryngeal mask in elective surgical procedures in the prone position.[2–6] Arguments in favour of this approach have been that the induction-to-incision time is reduced and that cardiovascular changes are reduced.[6] No randomised studies have compared the LM method with traditional endotracheal intubation in the supine position and subsequent movement into the prone position (the ET method). The latter position has a known association with a range of complications.[7] It is rarely argued whether the number and/or severity of these complications might be reduced by self-positioning in the prone position before induction of anaesthesia.[8]

The aim of the present study was to examine whether the LM method was superior to the ET method. Our primary hypothesis was that the LM method would be faster than the ET method. The primary end point was the total time taken from initial identification to readiness for radiographic examination of the patient, prone and anaesthetised. The secondary end points were airway complications during the surgery and hoarseness, sore throat and pain in muscles and joints postoperatively. We also noted major complications (paresis or severe pain) associated with positioning on the operating table. The study was not powered to reveal differences between the groups regarding these incidences, which should in this context, be regarded as hypothesis generating.

Patients and methods

The study was approved by The Capital Region of Denmark Regional Committee on Biomedical Research Ethics (journal number H-D-2008–086) on 13 October 2008 and by the Danish Data Protection Agency (journal number 2008-41-2861). The study was registered at www.clinicaltrials.gov (ID NCT01041352, 30 December 2009). This prospective, controlled, randomised trial was carried out in a single institution from 20 March 2009 to 29 March 2011. Written and oral informed consent were obtained from all patients prior to inclusion.

Eligible patients were those scheduled for spinal surgery estimated to last 2 h or less, who were within American Society of Anesthesiologists physical status classification groups I–II and with an age of 18 to 70 years. Other inclusion criteria were a normal neck, throat, and mouth anatomy, mouth opening at least 4 cm and a Mallampati score I–II. Exclusion criteria were a BMI more than $35\,kg\,m^{-2}$, predicted or known difficult airway, known difficult mask ventilation, decreased mobility in the neck (unable to rotate the head $>45^{o}$ or to extend the neck more than 80°), no radiographic examination at the outset, as the time 'ready to radiograph' was one of the time points used to determine the primary outcome measure, and the need for a rapid sequence induction.

Personal data were obtained the day before surgery. After arrival at the operating theatre, the patients were randomised to the LM method (the LM group) or to the ET method (the ET group) according to a random number list in sealed opaque envelopes packed by a person not participating in the study. During the identification procedure, the patient stated his or her name, and this time marked the starting point for determining the primary end point. Patients in the LM group now positioned themselves on the operating table (on a Wilson frame) with the arms abducted and resting above the head. The head was turned to the side of choice of the patient and rested on a horseshoe shaped pillow. Patients in the ET group remained in bed. In both groups, venous access was secured. Heart rate and rhythm, oxygen saturation (SO_2), non-invasive arterial blood pressure, end-tidal carbon dioxide tension and neuromuscular blockade by a train-of-four (TOF) were monitored.

In both groups, preoxygenation with 100% oxygen via a face mask and an infusion of remifentanil $30\,\mu g\,kg^{-1}\,h^{-1}$ were started simultaneously. When the patient could feel an effect of the infusion, anaesthesia was induced with propofol 2 to $3\,mg\,kg^{-1}$ followed by an infusion of propofol $10\,mg\,kg^{-1}\,h^{-1}$ (which was reduced to $5\,mg\,kg^{-1}\,h^{-1}$ after 5 min). When the eye lash reflex was absent, the lungs were ventilated with 100% oxygen using a face mask. Rocuronium $0.6\,mg\,kg^{-1}$ were administered to obtain neuromuscular relaxation. At a TOF ratio equal to 0, the laryngeal mask or endotracheal tube was inserted.

In the LM group, a ProSeal laryngeal mask (PLMS; GM Medical A/S, Birkeroed, Denmark) lubricated with a water-soluble gel was used. The size of the laryngeal mask was chosen according to the weight of the patient as recommended by the manufacturer (30 to 50 kg size 3, 50 to 70 kg size 4 and >70 kg size 5). A syringe without a plunger was attached to the cuff so that the pressure was 0 mmHg during the insertion of the laryngeal mask. The patient's face was turned sideways during the placement of the laryngeal mask. The digital insertion technique was used.[9] A gastric tube was inserted through the drain tube and the cuff of the laryngeal mask was inflated until the seal was complete [no audible sounds during positive pressure ventilation and no air leak measured by the anaesthesia machine (Primus; Dräger, Luebeck, Germany)]. The cuff pressure was measured with an Ambu cuff pressure gauge (Ambu, Copenhagen, Denmark). Positive pressure ventilation was applied using a pressure regulated volume controlled ventilation mode, in which the tidal volume and respiratory rate were chosen according to the weight of the

patient and an algorithm derived from a Radford diagram by the anaesthesia machine. If a complete seal was not obtained after the injection of 20, 30 or 40 ml for laryngeal mask size 3, 4 and 5, respectively (the maximum volume recommended), the laryngeal mask was repositioned or reinserted as decided by the anaesthetist. The laryngeal mask was defined as correctly placed when the gastric tube was in place and the seal was complete. Three attempts at reinsertion were allowed. The patient's bed stayed beside the operating table until the laryngeal mask was placed and no leak could be detected.

The patients in the ET group were anaesthetised in the supine position. Intubation was performed using a Macintosh laryngoscope and an oral endotracheal tube (Unomedical, Birkerod, Denmark) size 7.5 for women and 8.5 for men. The cuff was inflated until the seal was complete. The endotracheal tube was defined as placed correctly when the airway was sealed, respiratory sounds could be identified over both lungs and a CO_2 curve was seen on the capnograph. Then, a gastric tube was introduced and the patient was turned over and placed in the prone position on the operating table.

In both groups of patients, the lungs were ventilated with a 1 : 1 mixture of oxygen and air. The infusions of propofol and remifentanil were continued at the same rates. If deeper anaesthesia was needed – assessed by a sudden increase in peak pressure, tachycardia, hypertension, movements or an air leak – a bolus of remifentanil 60 to 120 μg was given and the infusion rate of remifentanil was increased by 10%. These manoeuvres were recorded. Hypotension was treated with additional fluid and ephedrine 5 mg intravenously. No additional dose of rocuronium was given unless requested by the surgeon. Immediately before the surgery a radiographic examination was carried out in order to identify the correct level of the surgical intervention. During the last part of the procedure, after the first closing suture, the infusion rate of both infusions was reduced to 50% and when the last suture was tied, both infusions were stopped. When there was a response to the laryngeal mask or to the endotracheal tube, it was removed, irrespective of whether the patient was back in bed or still on the operating table.

The primary outcome was defined as the total time from identification of the patient to readiness for radiographic examination (immediately before surgery), anaesthetised and prone. Secondary outcomes were airway problems during the surgery and sore throat, hoarseness and pain in the muscles and joints postoperatively. These perioperative complications were scored 0 = none, 1 = mild and 2 = severe. In addition, blood in the sputum and complications caused by the position on the operating table were registered 3 and 24 h after the procedure (in the recovery room and in the general ward, respectively). Blood on the laryngeal mask, on the endotracheal tube and in the sputum (macroscopic, dipstick) when the laryngeal mask or the endotracheal tube was removed were registered too. The staff that collected the data were blind to the randomisation.

Sample size

Statistical power analyses were based on times obtained from the anaesthetic cards of 10 patients anaesthetised as the LM group. The sample size was calculated using a minimum relevant difference in the primary outcome of 5 min and a standard deviation (SD) of 8 min. With α equal to 0.05 and a power of 90%, 55 patients in each group would be required. To compensate for the exclusion of patients, 70 patients were included in each group.

Statistical analysis

The χ^2 test or the Fischer's exact test for categorical data was used for analysis of data as required. For quantitative data, the *t*-test for normally distributed data or the non-parametric Mann–Whitney rank-sum test was used. The normality of the data was tested by the Shapiro–Wilk test. Statistical significance was defined as $P<0.05$. Values are expressed as mean (SD) or as median (interquartiles) [range] as appropriate. SigmaPlot 11.0 (Systat Software Inc., 2008, Chicago, USA) was used for all calculations.

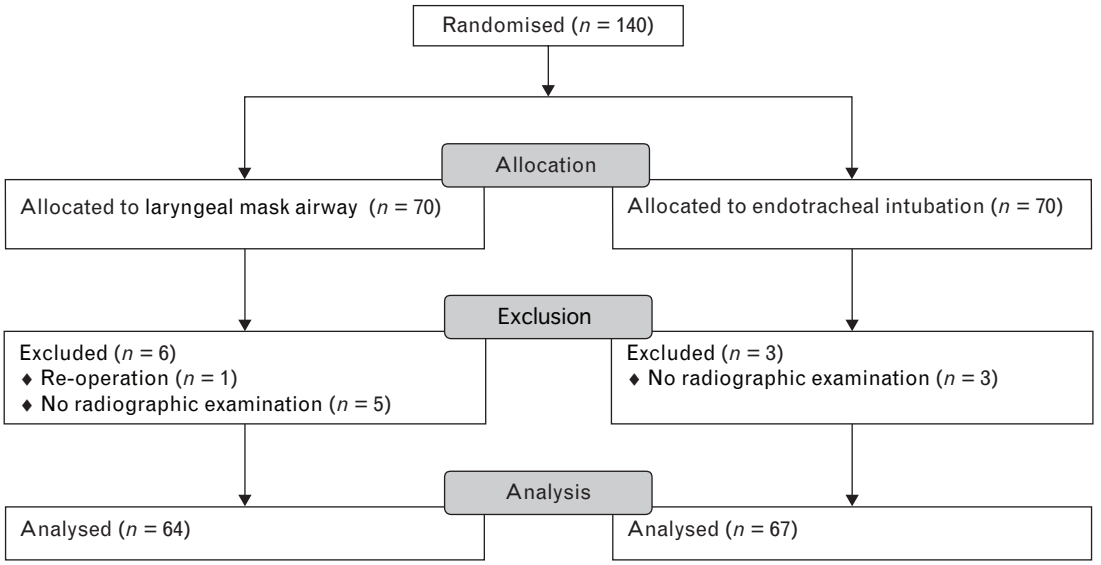
Results

A total of 140 patients were enrolled in the study. Nine patients were excluded (Fig. 1), leaving data from 64 and 67 patients in the two groups, respectively, for analysis. The personal characteristics of patients in the two groups were comparable (Table 1).

The time (median) from identification of the patient to readiness for radiographic examination was 5 min less in the LM group than in the ET group. This corresponds well to the 6 min taken from securing the laryngeal mask to readiness for radiographic examination, and the 12 min for the same interval in group ET (Table 2).

In two patients, it was not possible to obtain a complete air seal. Both patients were rolled back into bed, and were intubated there. One was returned to the prone position. For this patient, the total time from identification to readiness for radiographic examination was 40 min, that is 15 min longer than the median time in the LM group. Data shown including this patient ($n = 63$), and without ($n = 62$) are given in Table 2. The other patient was not returned to the operating table as the operation was cancelled due to an unacceptable low blood pressure. Even if both patients were included in the LM group (using 40 min for both patients), the difference between the median value in the LM and in the ET group would be unchanged. The *P* value for the difference between the groups (primary end point) would be unchanged too (non-parametric analysis). However, if parametric

Fig. 1



Flow diagram of study.

analysis was used (although data in one of the groups were not normally distributed), inclusion of both patients would reduce the difference between the mean values in the two groups from 4 to 3 min ($P = 0.003$).

The placement of the laryngeal mask, including insertion of a gastric tube as this was considered an integral part of the procedure took 36 s longer than securing the endotracheal tube (excluding time for insertion of the gastric tube). There was no significant difference between the groups with regard to the duration of surgery, emergence/extubation and stay in the recovery room. All recorded times are shown in Table 2.

There were no cases of respiratory distress, airway obstruction, laryngeal spasm or incomplete air seal during surgery. There were no signs of gastric insufflation or of aspiration due to an inadequate seal and in no patient was the SO_2 less than 92%. For differences between the groups as regards sore throat or hoarseness postoperatively, see Table 3.

Two patients (weight 90 and 95 kg, respectively) in group LM required an oral airway to facilitate mask ventilation. One patient (weight 88 kg) required two persons to insert the laryngeal mask. The laryngeal mask was placed in the first attempt in 48 patients and in two to three attempts in 14 patients. The cuff pressure in the laryngeal mask was 12 cmH_2O (0 to 30) [0 to 52]. In seven patients, all in the LM group, additional remifentanil was administered. The laryngeal mask and the endotracheal tube were removed in the prone position in 51 and 25 patients, respectively, whereupon they all moved themselves to the bed. There was no difference as regards blood on the laryngeal mask, on the endotracheal tube (macroscopic) or in the sputum.

There were no cases of paresis. Three hours postoperatively, there were fewer cases with pain in joints or muscles in the LM group than in the ET group, but no differences were found 24 h postoperatively. Two patients in the ET group had severe pain in muscles or joints (Table 3).

Table 1 Patient and group characteristics

	Laryngeal mask airway ($n = 63$)	Endotracheal tube ($n = 67$)
Age (years)	46 (13) [19 to 70]	47 (14) [19 to 70]
Sex (male/female) (*n*)	38/25	38/29
Height (cm)	179 (9) [150 to 194]	175 (8) [160 to 190]
Weight (kg)	77 (14) [50 to 109]	80 (11) [54 to 107]
BMI ($kg\,m^{-2}$)	24 (4) [17 to 34]	26 (3) [19 to 35]
Beard (*n*)	6	6

Data are mean (SD) [range] or absolute numbers.

Discussion

The main finding was that the total time from the identification to readiness of the prone, anaesthetised patient for radiograph examination was 3 to 5 min less using the LM method. This was subject to the choice of analysis and whether the two patients with the incomplete air seals were included. There were no airway-related complications during the surgery in any of the groups and although statistically significant differences between the groups with regard to sore throat, hoarseness or pain in muscles or joints were found at 3 h, there was no difference 24 h after the surgery.

Table 2 Duration of anaesthesia, surgery and stay in the recovery room in minutes

Time	Laryngeal mask airway	Endotracheal tube	*P*
	(*n* = 63)	(*n* = 67)	
Time from identification to readiness for radiograph	25 (23 to 29) [16 to 44]	30 (26 to 33) [17 to 47]	<0.001
	(*n* = 62)	(*n* = 67)	
Time from identification to readiness for radiograph	25 (22 to 29) [16 to 44]	30 (26 to 33) [17 to 47]	<0.001
Time from positioning the LM or ET to readiness for radiograph	6 (5 to 9) [1 to 17]	12 (9 to 15) [4 to 27]	<0.001
Time from picking up the LM or ET to securing the device in the correct position	1 : 36 (0 : 57 to 2 : 07) [0 : 25 to 7 : 40]	1 : 00 (0 : 36 to 1 : 43) [0 : 30 to 6 : 30]	<0.001
Duration of surgery	53 (35 to 69) [13 to 182]	52 (35 to 74) [12 to 246]	0.9
Time from last suture to removal of the LM or the ET	9 (5 to 13) [2 to 21]	7 (5 to 11) [1 to 20]	0.2
Time from the identification of the patient to leaving operating theatre	105 (89 to 125) [59 to 257]	108 (90 to 131) [70 to 378]	0.5
Stay in the recovery room	115 (82 to 150) [52 to 565]	111 (85 to 149) [45 to 245]	0.9

Data calculated with (*n* = 63) and without (*n* = 62) inclusion of one patient in the laryngeal mask group who had to be intubated. *P* values are calculated for non-parametric data. ET, endotracheal tube; LM, laryngeal mask.

The clinical relevance of this time difference is debatable. However, 5 min was exactly the time we chose as the minimum relevant difference for the power calculations and if several short operations in the prone position are performed every day, the cumulated time may be substantial. It could be argued that it was unnecessary to achieve neuromuscular blockade before insertion of the laryngeal mask and that the total time for induction and insertion of the laryngeal mask could be reduced accordingly. The effects of neuromuscular blockade on the insertion and on the seal pressure of laryngeal mask in patients in the prone position have not been studied. It is our practice to administer a neuromuscular blocking drug to facilitate endotracheal intubation and we chose to administer rocuronium to both groups to improve standardisation. Furthermore, most of our surgeons require the patients to be relaxed during the first part of the surgery.

As a safety prerequisite for the laryngeal mask method, the bed always stayed beside the operating table until the laryngeal mask airway was completely established and during this period at least one assistant was in the theatre. Generally, we experienced no problems in obtaining a reliable airway with the laryngeal mask. However, two of the 64 patients (or 70 as all the six excluded patients in this group had the laryngeal mask placed uneventfully) had to be excluded, as it was not possible to obtain a complete air seal. One was a 108 kg man (BMI 33) and the other an 88 kg (BMI 30) woman. In both patients, a size 4 as well as a size 5 PLMS was inserted without obtaining a complete air seal and eventually an endotracheal tube was placed. In the clinical setting, a small air leak might be accepted by some anaesthetists. Others would probably consider this to be unacceptable for a patient placed in the prone position. Both patients were rolled back into bed and intubated there. One of the two patients was large and it may be that the LM method should be avoided in patients over a certain weight (or BMI). This patient was intubated and had an uneventful procedure. The other patient was not returned to the operating table due to hypotension that failed to respond to treatment with

Table 3 Complications registered 3 and 24 h after anaesthesia

	Time	Score	Laryngeal mask airway *n*	Endotracheal tube *n*	*P*
Sore throat	3 h	0	59	51	0.004
		1	1	16	
		2	2	0	
	24 h	0	51	53	0.7
		1	8	12	
		2	3	2	
Hoarseness	3 h	0	44	36	0.045
		1	17	30	
		2	1	1	
	24 h	0	52	47	0.08
		1	8	19	
		2	2	1	
Pain in joints or muscles	3 h	0	59	58	0.03
		1	3	7	
		2	0	3	
	24 h	0	59	58	0.09
		1	3	7	
		2	0	2	

0 = none; 1 = mild; 2 = severe.

fluid and inotropes. After anaesthesia, the blood pressure returned to normal spontaneously. The hypotension in this patient with type II diabetes probably was caused by a combination of dehydration, an angiotensin-converting enzyme inhibitor and amitriptyline. A diagnosis of orthostatic hypotension was made by a cardiologist.

Even though inclusion of the two patients only marginally influenced the *P* values, the time used for intubation and re-positioning is a relevant issue. The LM method may be rejected by clinicians if more than a very few patients have to be intubated and re-positioned. Thus, in order to eliminate this complication, future studies should focus on the question of which categories of patients are really suitable for this method.

As shown in Table 2, one patient (69 years old) in the LM group stayed for more than 9 h in the recovery room. This prolonged stay was due to a need for oxygen and periods of apnoea probably caused by the significant dose of opioid required to relieve postoperative pain. There were no signs of regurgitation or aspiration.

A substantial number of patients have been anaesthetised using the LM method without major complications[2–6] and in several studies, the laryngeal mask has been found to be an effective and useful alternative to the endotracheal tube for anaesthesia in the prone position.[3,5,6,10] One study comparing different types of laryngeal masks in the prone position has been carried out.[11] In that study, the LMA Supreme was compared to the PLMS. The airway was efficiently managed with both devices, although the PLMS required fewer manipulations and achieved a higher seal pressure. The data from the LM group in our study are comparable with these studies, although more reinsertions were necessary in our study and the insertion time was slightly longer. Ng *et al.*[5] found that insertion of the PLMS could be learned in about 10 supervised cases and Sharma *et al.*[3] showed that the first-pass success rate was 90.5% for anaesthesia trainees. One explanation for the difference could be that although the nurse anaesthetists who inserted the laryngeal mask in our study were very experienced with it in the supine position, they had a limited experience (a minimum of five times) with placing a PLMS in the prone position. Another explanation could be that, as the placement of a gastric tube was considered part of the laryngeal mask placement procedure, the insertion of the laryngeal mask in our study was defined as completed only when the gastric tube was in place and no leak could be registered. Thus, even with an insignificant seal failure (with the maximum amount of air in the cuff), the laryngeal mask was re-positioned, reinserted or changed to another size. Overall, the LM method seems to be safe, but before a more definitive answer can be given, more patients should be studied as severe safety problems are rare.

It is well known that the prone position is associated with a number of different complications.[12] These include low incidences of arterial or venous occlusion, cervical spine injury and peripheral nerve injury. The incidence of the latter, including both reversible and irreversible symptoms, is 2 to 7%, in the upper limb, and up to 24% in the lower limb.[12] There is disagreement as to the best form of the prone position and it is of note that when analysing closed claims data, reviewers felt that an appropriate standard of care was met in the majority of cases.[7,13] Accordingly, it has been proposed that the patient's ability to tolerate the proposed position should be tested while they are awake.[13,14]

At 3 h, but not at 24 h postoperatively, fewer complications associated with the position on the operating table (pain in muscles and joints) were found in the LM than in the ET group. Two cases with severe discomfort were found in the ET group. An attractive theory is that a sufficiently powered study would confirm that self-positioning before induction of anaesthesia could reduce the number of injuries to shoulders, elbows, nerves, muscles and other tissues.

Conclusion

In conclusion, the present study shows that the LM method as performed in this study is a few minutes faster than the ET method. There was nothing to indicate that the LM method is unsafe. Self-positioning saves on manpower. Two patients, in whom a tight air seal could not be obtained, may be a concern. More studies are needed to decide whether the LM method should be avoided in certain groups of patients. Finally, it would be useful in a larger study to test the hypothesis that self-positioning reduces the number of major complications associated with positioning on the operating table.

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Presentation: none.

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