Journal of Clinical Monitoring and Computing (2020) 34:285–294
https://doi.org/10.1007/s10877-019-00301-3

ORIGINAL RESEARCH

A prospective randomized comparison of airway seal using the novel vision-guided insertion of LMA-Supreme® and LMA-Protector®

André A. J. van Zundert[1,5] · Kerstin H. Wyssusek[1] · Anita Pelecanos[2] · Michelle Roets[1] · Chandra M. Kumar[3,4]

Received: 14 August 2018 / Accepted: 18 March 2019 / Published online: 5 April 2019

Abstract

The laryngeal mask airways supreme (LMA-Supreme™) and protector (LMA-Protector™) are generally placed blindly, often resulting in a less than optimal position and vision-guided placement has been recommended. This prospective, randomized controlled study compared the efficacy of airway seal by measuring the oropharyngeal leak pressure in 100 surgical patients who underwent a variety of non-thoracic surgery under general anaesthesia, suitable with a supraglottic airway device. Patients were allocated to either the LMA-Supreme (n = 50) or LMA-Protector (n = 50) group. All insertions were performed under vision of a videolaryngoscope using an 'insert-detect-correct-as-you-go' technique with standardized corrective measures. Our primary endpoint, mean oropharyngeal leak pressure, was significantly higher in the LMA-Protector (31.7 ± 2.9 cm H_2O) compared to the LMA-Supreme (27.7 ± 3.5 cm H_2O) group (mean difference 4.0 cm H_2O, 95% confidence interval (CI) 2.7–5.3 cm H_2O, p < 0.001) after achieving a near-optimal fibreoptic position in the LMA-Protector (94%) and LMA-Supreme (96%) groups. No statistically significant differences were shown for secondary outcomes of alignment, number of insertion attempts and malpositions, and final anatomical position as scored by fibreoptic evaluation. Corrective manoeuvres were required in virtually all patients to obtain a correct anatomically positioned LMA. Position outcomes of the two devices were similar except for the proportion of procedures with folds in the proximal cuff (90% LMA-Supreme vs. 2% LMA-Protector, $p < 0.001$), the need for intracuff pressure adjustments (80% LMA-Supreme vs. 48% LMA-Protector, $p = 0.001$) and size correction (18% LMA-Supreme vs. 4% LMA-Protector, $p = 0.025$). In conclusion, a higher oropharyngeal leak pressure can be achieved with LMA-Protector compared to LMA-Supreme with optimal anatomical position when insertion is vision-guided.

Keywords Airway · Supraglottic airway device · Video-laryngoscopy · LMA-Supreme · LMA-Protector · Oropharyngeal leak pressure

1 Introduction

At present, supraglottic airway devices (SGADs) are used for the overall majority of devices in airway management [1]. Blind placements of SGADs result in 50–80% aberrant positions previously confirmed by radiological studies, fibreoptic viewings, ultrasound confirmation and clinical findings [2–7]. These may result in suboptimal airway control, leaking or obstructed airways and insufficient gas exchange. Recent research findings confirmed incorrect positioning of

✉ André A. J. van Zundert
vanzundertandre@gmail.com

Kerstin H. Wyssusek
kwyssusek@gmail.com

Anita Pelecanos
Anita.Pelecanos@qimrberghofer.edu.au

Michelle Roets
michelleroets@gmail.com

Chandra M. Kumar
chandra.kumar2406@gmail.com

1 Department of Anaesthesia and Perioperative Medicine, Royal Brisbane and Women's Hospital, The University of Queensland, Brisbane, QLD, Australia

2 Statistics Unit, QIMR Berghofer Medical Research Institute, The University of Queensland, Brisbane, QLD, Australia

3 Department of Anaesthesia, Khoo Teck Puat Hospital, Yishun Central, Singapore

4 Newcastle University, Newcastle, UK

5 Queensland University of Technology, Brisbane, QLD, Australia

most existing SGADs and a beneficial vision-guided SGAD insertion flow chart was proposed and recommended with corrective manoeuvres that can be used for "failed supraglottic airways", which significantly improved positioning of the airway [8–10].

LMA®-Protector™ Airway (Teleflex Medical, Westmead, Ireland) has recently been introduced in clinical practice as a new SGAD. It has several similarities to PVC-made LMA®-Supreme™ Airway, except it is made almost entirely (cuff and airway tube) of medical-grade silicone [11]. Newer devices have several features that increase safety relating to the prevention of gastric aspiration through an adequate oropharyngeal seal and enhanced oropharyngeal leak pressure (OLP). OLP is often used to assess safety, efficacy, and degree of airway protection, providing an indication of device positioning after blind insertion [12–14]. However, the assumption of OPL being an accurate and useful indicator of an airway leak is subject to a SGAD being optimally placed [10, 15].

SGAD size is usually chosen based on weight, height, gender or anatomical features, although no single system provides a comprehensive solution [16]. Vision-guided placement of SGADs offers benefits and it becomes apparent that the device size needs changing or further manipulation may be required to obtain an optimal position and seal of the airway.

This prospective randomized study compared our primary outcome of OPL of the airway of vision-guided insertion of LMA Protector (LMA-P) and LMA Supreme (LMA-S). OPL of LMA-P was hypothesized to be higher than LMA-S. Secondary aims included comparing LMA-P and LMA-S (a) insertion outcomes (choice of SGAD size, ease and number of insertion attempts, manipulations required), (b) adequacy of ventilation and adjustments of intracuff pressure, (c) incidence of airway trauma and (d) positioning outcomes (size of videolaryngoscope blade used, incidence of malpositioning, use of corrective manoeuvres and different SGAD size/brand, final position of epiglottis/vocal cords with fibreoptic scopes).

2 Materials and methods

The Royal Brisbane and Women's Hospital Human Research Ethics Committee (HREC/15/QRBW/248, Chairperson Dr. Conor Brophy, dd 03.07.2015) approved the study. This study was registered with the Australia and New Zealand Clinical Trial Registry (ACTRN12615000783527). Written patient's informed consent was obtained involving 100 consecutive patients undergoing general anaesthesia suitable for vision-guided airway maintenance with SGADs (LMA-S or LMA-P), performed at a tertiary university hospital (July 2015-June 2016). Exclusion criteria included: (i) age < 18 years; (ii) ASA physical class > 3; and (iii) pregnant patients, patients with a potential risk of regurgitation and head and neck operations. Allocation into LMA-P and LMA-S study arms was randomized using computer-generated randomization codes, placed into sealed envelopes by a research nurse independent of the study and consecutively opened by the treating anaesthetist immediately prior to each induction. Given the visual differences between the two devices, the anaesthetist could not be blinded.

The position of SGADs was considered anatomically and functionally optimal when the: (i) correctly-sized device (weight-based) was seated properly within the hypopharynx; (ii) inflated cuff produced an adequate seal between the device and glottis entrance (first seal) and distal cuff of a second-generation SGAD blocked the entrance of the oesophagus (second seal) allowing the ventilation opening of the SGAD tube to oppose the glottis opening and trachea; and (iii) epiglottis rested on the outside of the device, its tip aligned to the rim of the inflated proximal cuff [8, 10]. We assessed adequacy of SGAD airway seals by measuring the OPL reading from the anaesthesia machine, the pressure at which a gas leak occurs around the device (audible noise over the mouth), determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L min^{-1}. For safety concerns, airway pressure was permitted to increase to the maximal allowable OLP of 40 cm H_2O.

All SGADs were placed by the same anaesthetist (AVZ) who has extensive experience using a wide range of SGADs, including LMA-S and LMA-P, inserted under videolaryngoscopic vision-guidance and an "insert-detect-correct-as-you-go" technique for optimal positioning following standard corrective manoeuvres to facilitate an unobstructed airway [8–10]. Indeed, anaesthetists should aspire to improving the quality of SGAD insertions as blindly inserted devices are often malpositioned. All malpositions can be corrected by applying jaw thrust and chin lift. Improved insertion conditions can be obtained by elevating the epiglottis from the insertion path, increasing the anteroposterior diameter of the pharynx as well as the distance between the base of the tongue and the posterior pharyngeal wall. Visualisation with the (video) laryngoscope helps to immediately detect and correct downfolding and double folding of the epiglottis, distal cuff misplacement and backward folding, proximal SGAD cuff displacement and cuff folding that may result in airway gas leaks, airway obstruction and impaired gas exchange. Visualisation of SGAD insertion allows immediate recognition and correction of substandard cuff inflation, incorrect SGAD size and glottis distortion.

No pre-medication was administered. Anaesthesia management included: (i) standard monitoring and pre-oxygenation with a facemask for 3 min; and (ii) induction with intravenous lidocaine (0.5–1 mg kg^{-1}), fentanyl (1.5–2 µg kg^{-1}), propofol (2.5–3 mg kg^{-1}) and sevoflurane with 50% oxygen

and air. If necessary during videolaryngoscopy, additional propofol was administered.

The SGAD was completely deflated, and water-based lubricant applied to the posterior surface of the SGAD cuff. C-MAC™ videolaryngoscope (Karl Storz®, Tuttlingen, Germany) blades 3 and 4 were used to assist in the optimal positioning. Insertion without jaw thrust simulated a blind insertion. Any malpositioning (initial downfolding of the epiglottis, distal cuff sitting between and across vocal cords, distal cuff folding over backwards, folds in proximal cuff, epiglottis malpositioning in the bowl and sideways folding or double folding of epiglottis) was noted as well as mis-alignment between the tip of the epiglottis and rim of the proximal cuff due to deep or superficial placement of SGADs, small or large-sized SGADs, and hyperinflated or underinflated SGAD cuffs [8]. Location of the epiglottis in the bowl of the device was scored as 0 (tip of epiglottis not in the bowl of the device), 1 (overt epiglottic downfolding, spontaneously restored), 2 (epiglottic downfolding, resumes its normal position by using active manoeuvres), or 3 (unable to be evaluated). Jaw thrust elevated the epiglottis and increased the distance between the posterior aspect of the tongue and posterior pharyngeal wall. This allowed visualization of the device, verification of the exact position of different aspects of the SGAD (distal cuff, proximal cuff, epiglottis, and size of SGAD) and placement in the imagined correct anatomical position.

Once the SGAD was considered positioned correctly as described above, the cuff was inflated using a handheld aneroid cuff pressure manometer monitor (Portex® Hythe, UK) aiming to inflate the cuff until an intracuff pressure of 60 cm H_2O was obtained. If an optimum position of SGAD was not achieved after two attempts, an alternative SGAD (LMA-Classic or i-gel) was used based on hospital protocol.

Data collection by an independent research assistant included: patient's characteristics (Table 1) as well as premetrics of airway difficulties, type of surgery, duration of anaesthesia, ventilation adequacy, OLP (primary outcome) and secondary outcomes (i) choice of SGAD size; (ii) number of vision-guided SGAD insertion attempts, ease of SGAD insertion, number of manipulations required to obtain an optimal position of the device; (iii) ventilatory status of the device in situ (incidence of normal ventilation, audible leak, indication of desaturation); (iv) monitoring aspects (capnogram, intracuff pressure adjustments); and (v) incidence of airway trauma (blood on SGAD at the time of removal, trauma to lip/mucosa/teeth, incidence of sore throat at 2 h post-operation in recovery) (Table 2). Exploratory SGAD position outcomes included: (i) size of videolaryngoscope blade used; (ii) incidence of initial (mal)positioning of SGADs and epiglottis and (mal)alignment of the tip of epiglottis and rim of proximal cuff SGAD; (iii) use of corrective manoeuvres and the use of a different size/brand of SGAD;

Table 1 Patient demographics and other relevant data related to both SGAD groups

Variables	LMA-Supreme ($n=50$)	LMA-Protector ($n=50$)
Gender		
Male	26 (52%)	27 (54%)
Female	24 (48%)	23 (46%)
Age (years)	42.6 ± 15.5	43.1 ± 18.3
Height (cm)	169.1 ± 10.3	172.0 ± 10.2
Weight (kg)	78.5 ± 15.7	79.1 ± 18.0
BMI (kg m^{-2})	26.5 (23.0–30.8)	26.0 (23.0–28.8)
ASA		
I	24 (48%)	29 (58%)
II	22 (44%)	18 (36%)
III	4 (8%)	3 (6%)
Dentition		
Top and bottom	44 (88%)	47 (94%)
Top or bottom	6 (12%)	3 (47%)
Mallampati grade		
I	15 (30%)	25 (50%)
II	28 (56%)	24 (48%)
III	7 (14%)	1 (2%)
Prominent canine on right side		
No	48 (96%)	50 (100%)
Yes	2 (4%)	0 (0.0%)
Interincisor distance (mouth opening) (mm)	41.3 ± 7.9	43 ± 4.0
Thyromental distance (mm)	73.1 ± 11.8	78.5 ± 12.5
Sternomental distance (mm)	130.3 ± 20.7	136.9 ± 18.0
Neck mobility		
>90°	47 (94%)	47 (94%)
<90°	3 (6%)	3 (6%)
Neck circumference (cm)	37.9 ± 3.6	37.4 ± 4.8
Upper lip bite test (grade)		
I = Perfect	19 (38%)	31 (62%)
II = Partially	25 (50%)	17 (34%)
III = Not capable	6 (12%)	2 (4%)
Type of surgery		
General surgery	2 (4%)	5 (10%)
Orthopaedics	17 (34%)	17 (34%)
Gynaecology	15 (30%)	8 (16%)
Plastic surgery	13 (26%)	11 (22%)
Urology	3 (6%)	9 (18%)
Anaesthesia duration (min)	65.0 (42.0–86.5)	70.0 (42.0–106.2)
Ventilation		
Spontaneous	42 (84%)	40 (80%)
Artificial	8 (16%)	10 (20%)

Data expressed as number (%), mean ± SD or median (IQR (Quartile 1—Quartile 3)); *BMI* body mass index

Table 2 Insertion outcomes

Insertion outcomes	LMA-Supreme ($n=50$)	LMA-Protector ($n=50$)	p value
Initial SGAD choice size			
3	1 (2%)	2 (4%)	
4	27 (54%)	22 (44%)	0.23
5	22 (44%)	26 (52%)	
Insertion attempts			
1	28 (56%)	36 (72%)	0.096
2–3	22 (44%)	14 (28%)	
Ease of insertion			
Easy	34 (68%)	35 (70%)	0.83
Moderate and with resistance	16 (32%)	15 (30%)	
Manipulation required			
No	7 (14%)	3 (6%)	0.18
Yes	43 (86%)	47 (94%)	
Normal ventilation			
No	3 (6%)	0 (0%)	0.24
Yes	47 (94%)	50 (100%)	
Audible leak at mouth			
No	47 (94%)	49 (98%)	0.62
Yes	3 (6%)	1 (2%)	
Desaturation during SGAD insertion			
No	47 (94%)	49 (98%)	0.62
Yes	3 (6%)	1 (2%)	
Normal capnogram			
No	2 (4%)	0 (0%)	0.50
Yes	48 (96%)	50 (100%)	
Intracuff pressure adjusted			
No	10 (20%)	26 (52%)	0.001
Yes	39 (80%)	24 (48%)	
Blood at SGAD at removal			
No	35 (70%)	36 (72%)	0.83
Stain or visual	15 (30%)	14 (28%)	
Trauma to lips, tongue, mucosa			
No	50 (100%)	49 (98%)	1.00
Yes	0 (0%)	1 (2%)	
Airway morbidity in recovery			
None	44 (88%)	44 (88%)	1.00
Sore throat or dysphonia	6 (12%)	6 (12%)	

Data expressed as number (%)

(iv) final position of epiglottis relative to the SGAD; and (v) whether or not vocal cords and epiglottis could be visualized during fibreoptic evaluation (Table 3). Fibreoptic score was graded as: grade I (vocal cords and posterior epiglottis seen but tip of the epiglottis not visible); grade II (part of vocal cords and posterior epiglottis seen, including tip of epiglottis sitting in the bowl of SGAD); grade III (part of glottis seen and anterior aspect of epiglottis visible); and grade IV (only anterior aspect of epiglottis seen with no part of glottis visible). Percentage of glottis opening (POGO) scores [17] and Cormack-Lehane grades [18] before and after jaw lifting were recorded (Table 4).

2.1 Statistical analysis

Sample size was calculated based on the primary outcome of OPL, measured on a continuous scale. Summary data from a 2014 meta-analysis by Maitra et al. [12] allowed the assumption that OPL would be normally distributed with a standard deviation 5 cm H_2O. Based on this data, the participant

Table 3 Exploratory analyses of SGAD position outcomes

SGAD position outcomes	LMA-Supreme ($n=50$)	LMA-Protector ($n=50$)	p value
Evaluation using videolaryngoscope			
Videolaryngoscope blade size			
3	37 (74%)	28 (56%)	
4	13 (26%)	22 (44%)	0.059
Initial downfolding of epiglottis			
No	12 (24%)	11 (23%)	
Yes	38 (76%)	37 (77%)	0.90
Distal cuff between/across vocal cords			
No	47 (94%)	46 (96%)	
Yes	3 (6%)	2 (4%)	1.00
Distal cuff folding over backwards			
No	48 (96%)	47 (98%)	
Yes	2 (4%)	1 (2%)	1.00
Proximal cuff folding			
No	5 (10%)	49 (98%)	
Yes	45 (90%)	1 (2%)	< 0.001
Cuff in midline			
No	1 (2%)	0 (0%)	
Yes	49 (98%)	50 (100%)	1.00
Epiglottis in bowl			
Grade 0	11 (22%)	16 (33%)	
Grades 1–3	39 (78%)	32 (67%)	0.21
Correction with jaw lift			
No	2 (4%)	0 (0%)	
Yes	48 (96%)	50 (100%)	0.50
Sideways epiglottis downfolding			
No	46 (92%)	47 (94%)	
Yes	4 (8%)	3 (6%)	1.00
Alignment rim cuff SGAD tip epiglottis			
Perfect alignment	43 (86%)	47 (98%)	
No alignment	7 (14%)	1 (2%)	0.06
SGAD size correction needed			
No	41 (82%)	48 (96%)	
Yes	9 (18%)	2 (4%)	0.025
Different SGAD brand needed			
No	48 (96%)	50 (100%)	
Yes	2 (4%)	0 (0%)	0.50
Correction with Magill forceps			
No	49 (98%)	49 (98%)	
Yes	1 (2%)	1 (2%)	1.00
Railroading insertion technique			
No	48 (96%)	49 (98%)	
Yes	2 (4%)	1 (2%)	1.00
Final position epiglottis outside SGAD cuff			
No	0 (0%)	1 (2%)	0.49
Yes	48 (100%)[a]	49 (98%)	
Evaluation using fibrescope			
Visualisation vocal cords and epiglottis			
Grade I	48 (96%)	47 (94%)	
Grade II	2 (4%)	3 (6%)	1.00
Cuff optimal and in midline			
No	0 (0%)	1 (2%)	
Yes	50 (100%)	49 (98%)	1.00

Table 3 (continued)

Data expressed as number (%)

[a]A different brand of SGAD was needed in 2 of the 50 patients

Table 4 POGO scores and Cormack-Lehane grades before and after jaw lifts for each device

Before jaw lift	After jaw lift	LMA-Supreme ($n=50$)	LMA-Protector ($n=50$)
Cormack-Lehane			
Grade 1–2	Grade 1–2	5 (100%)	4 (100%)
	Grade 3–4	0 (0%)	0 (0%)
Grade 3–4	Grade 1–2	42 (93%)	45 (98%)
	Grade 3–4	3 (7%)	1 (2%)
POGO score			
0%[a]	0%	5 (11%)	0 (0%)
	> 0%	39 (89%)	47 (100%)
> 0%[b]	0%	0 (0%)	0 (0%)
	> 0%	6 (100%)	3 (100%)

Data expressed as number (%)

[a]No view or [b]partial/complete view of vocal cords

number 50 intervention and 50 control participants were calculated. The sample size used an independent t-test with a power of 80% to detect a difference of 3 cm H_2O between groups, a 2-sided type I error or 0.05 and accounted for a potential 10% drop-out rate.

Results are expressed as number (percent) for categorical variables, mean ± standard deviation (SD) for symmetrically distributed continuous variables or median [interquartile range (IQR)] for asymmetrically distributed continuous variables. The difference in OPL between LMA groups was compared using a Student's t-test. Other outcome variables were categorical and were compared between LMA groups with either Chi square or Fisher's exact tests (for small cell counts). A p value of < 0.05 was deemed statistically significant. Analyses were performed in R: Language and Environment for Statistical Computing version 3.3.1 (R-Core Team (2016), Vienna, Austria).

3 Results

The CONSORT flow diagram is shown in Fig. 1. We recruited 102 adult patients although two patients declined to participate in the study, leaving 100 patients for further analysis (50 in each LMA group). Table 1 includes patient's demographics and other relevant data. Both groups were similar in characteristics. The LMA-S group tended to have more Mallampati grades III patients and more patients were not capable of performing upper lip bite test (lower incisors

CONSORT
TRANSPARENT REPORTING of TRIALS

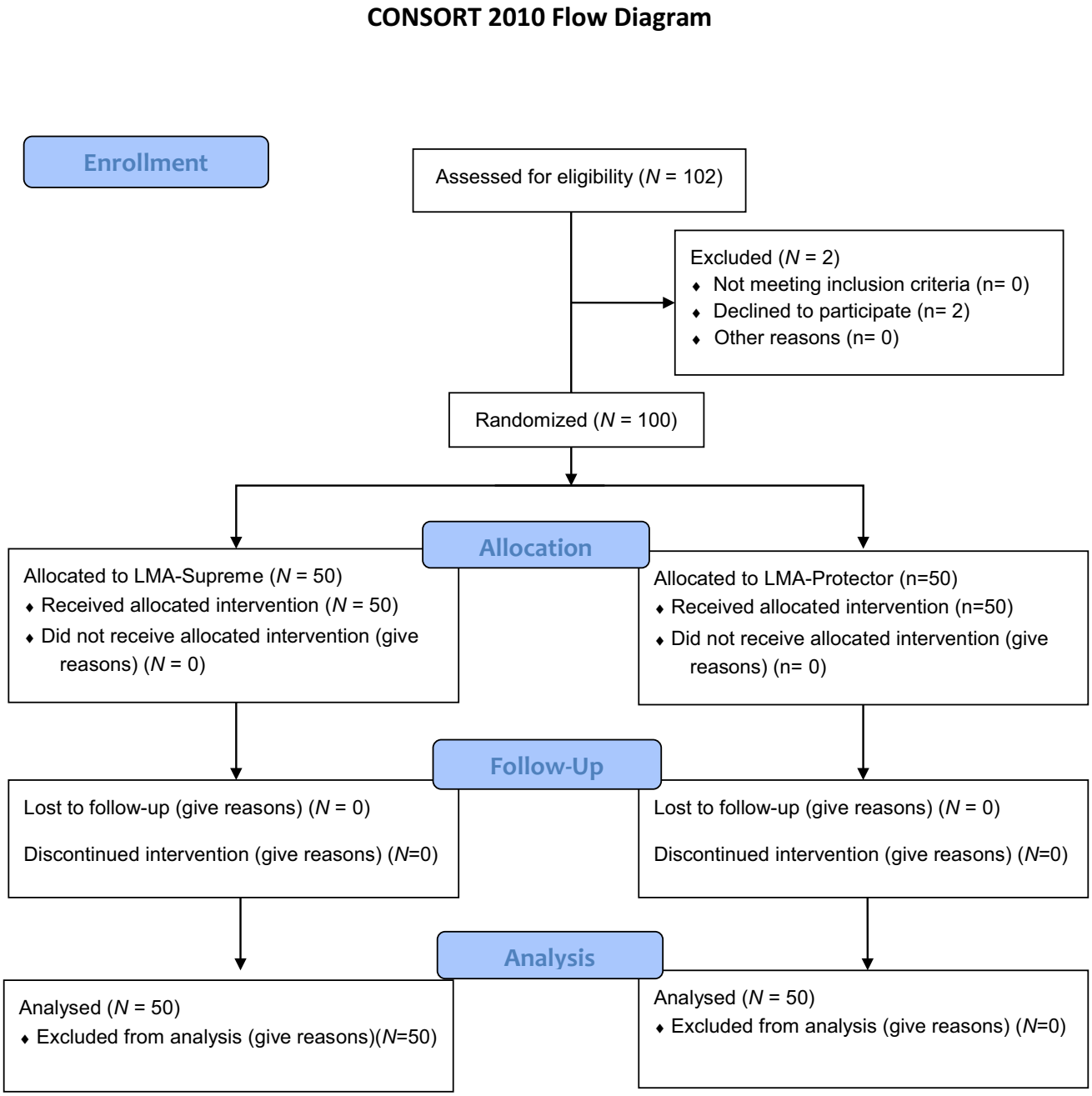

Fig. 1 The CONSORT flow diagram summarizing patient enrollment

can hide the mucosa of the upper lip: (I) completely; (II) partially; or (III) not at all).

Regarding the primary outcome, the LMA-P group had a statistically significant higher ($p < 0.001$) mean OPL (31.7 ± 2.9 cm H_2O) than the mean OLP (27.7 ± 3.5 cm H_2O) recorded in the LMA-S group (difference of means 4.0 cm H_2O, 95% confidence interval (CI) 2.7–5.3 cm H_2O).

Tables 2 and 3 outline the secondary insertion and position outcomes for both devices using videolaryngoscopy and fibreoptic evaluation.

Initial SGAD size choices for LMA-S:LMA-P were size 3 (1:2); size 4 (27:22) and size 5 (22:26). Categories grouped together for analyses were: (i) number of insertion attempts: 2 (n = 32) and 3 (n = 4); (ii) ease of insertion: moderate resistance (n = 25) and with resistance (n = 6); (iii) blood at SGAD at removal: stain (n = 22) and visual blood (n = 7); (iv) airway morbidity: sore throat (n = 11) and dysphonia (n = 1); (v) epiglottis in the bowl of device: grades 1 (n = 9), 2 (n = 59) and 3 (n = 3).

Adequacy of ventilation after correct LMA insertion, measured by capnograph trace was within the normal physiological range except for two LMA-S cases (Table 2). The measurement of intraoperative intracuff pressure was helpful in indicating inadequate placement. Intracuff pressure was adjusted more often in the LMA-S group (80% vs. 48%, $p < 0.001$). Final mean intracuff pressure measured was 57 ± 26 cm H_2O in LMA-S and 58 ± 21 cm H_2O in LMA-P group. This resulted in a correct OPL above 25 cm H_2O in all cases.

Vision-guided insertion aided by a videolaryngoscope blade 4 was used more frequently with LMA-P than LMA-S (Table 3). A size 3 blade was sought most of the time although it was unavailable in some cases. Number of SGAD insertion attempts, ease of insertion and incidence of manipulations needed, did not differ between the groups. Incorrect SGAD positioning (before correction) occurred in the majority of patients in both LMA groups, specifically initial epiglottis downfolding (76% vs. 77%); distal cuff sitting between and across the vocal cords (6% vs. 4%); distal cuff folding over backwards (4% vs. 2%); folds in the proximal cuff (90% vs. 2%, $p < 0.001$); cuff outside the midline (2% vs. 0%); epiglottis positioned in bowl of airway device with spontaneous return (78% vs. 67%) or use of jaw lifting (96% vs. 100%); and epiglottis folded double or sideways (8% vs. 6%). Corrections of malpositioned SGADs (Table 3) could easily be achieved by using vision-guided insertion technique and jaw lift manoeuvre (LMA-S 96% vs. LMA-P 100%). Despite predetermined SGAD selection based on a patient's weight, size correction was required in some cases because SGADs were inserted too deep or too superficial, SGADs were too small or too large, the cuff was hyper- or hypoinflated, or alignment between the tip and the rim of proximal the cuff could not be obtained. There were eight patients with no alignment of the rim of the proximal cuff with the tip of epiglottis. An alternative SGAD size had to be inserted ($p = 0.025$) in nine cases of LMA-S (18%) and two cases of LMA-P (4%). A different brand of SGAD was required in two cases of LMA-S. In the first case, this was due to the rigid PVC tube of LMA-S (both sizes 4 and 5 attempted) not conforming to the patient's airway anatomy. In the second case even the stem of a size 5 was not long enough to insert the device deep enough in the hypopharynx to obtain alignment with the epiglottis, leaving the epiglottis in the bowl of the device. In both respective instances a size 4 i-gel and a size 4 LMA-Classic resulted in perfect positioning of device. For one case in each device group, Magill forceps was needed to correct the double folded epiglottis. Two cases in the LMA-S and one in the LMA-P group required a railroading insertion technique to bring the device into the optimal position.

The success rate of vision-guided SGAD manoeuvres improved from 50 to 80% incorrect blind insertions to a near-optimal fibreoptic position in the LMA-S (96%) and in the LMA-P (94%) groups (Table 3). Visualization of the glottis and visibility of the posterior aspect of epiglottis (but not the tip of epiglottis) was obtained in 48 and 47 cases respectively. Only the tip of the epiglottis was visible in 2 (LMA-S) and 3 (LMA-P) cases. Except in one case, fibreoptic evaluation confirmed the optimal midline placement of original videolaryngoscopic (vision)-guided cuff position. The final position of both devices, as scored with videolaryngoscope and fibreoptic scope, did not differ.

At the time of SGAD removal, blood or blood stain was noticed in 30% or less of patients in both groups, whereas no dental trauma was observed and only 1 LMA-P case had a minor lip trauma (Table 2). Six patients in both groups presented with a minor sore throat (VAS score < 4) at 2 h postoperatively in recovery, for which no treatment was required.

Table 4 shows changes in POGO and Cormack-Lehane grades, scored before (resembling blind insertion) and after patient's jaw was lifted (with videolaryngoscope), indicating a substantial improvement in scores. The number of patients with a Cormack-Lehane grade III–IV substantially decreased and the number of patients with a greater than 0% POGO score substantially increased after jaw lift in both groups.

4 Discussion

This is the first study that demonstrates that vision-guided insertion of adequately-sized second-generation SGADs (LMA-S and LMA-P), positioned in an anatomically and functionally optimal position, results in an adequate OLP, which was significantly higher in LMA-P patients (mean 31.7 vs 27.7 cm H_2O). The value of OPL and intracuff

pressure in earlier studies may be questioned if optimal SGAD placement is not achieved.

Vision-guided SGADs insertion combined with standardized manoeuvres allowed visual adjustment of SGADs to their final anatomically correct position and virtually ruled out malpositioning. This is a significant improvement compared to 50–80% malpositions with a blind insertion technique [2–7]. Initial blind insertion resulted in epiglottis downfolding and positioning of epiglottis in the bowl of the device in > 75% of cases. This was not unexpected as both devices resemble each other in many aspects. All initial malpositions (e.g. wrong anatomical position of the distal and proximal cuff and epiglottis, wrong size or inadequately inflated cuff), could easily be corrected by inserting the device further into the oral cavity, using jaw thrust corrective manoeuvres and applying an "insert-detect-correct-as-you-go" principle [10].

Position was confirmed by fibreoptic evaluation where vocal cords were clearly seen, often with the posterior part of epiglottis visible (but not the tip), and with the cuff optimally placed in the midline. Vision-guided SGAD insertion may further eliminate a need for fibreoptic checks, reducing cost and time.

This study revealed a significant drawback of the guiding handle (fixation tab meant for securing the device) which may prevent deeper insertion of the device to ensure firm contact in the oesophagus and reach an optimal functioning anatomical position and airway seal. The fixation tap may cause the device to sit superficially and may result in an inability to oppose the LMA's tube and glottis entrance. This impacted on the number of insertion attempts. Other SGADs (e.g. LMA-Classic or i-gel) do not have these fixation tabs and allow deeper insertion of the device if needed. We believe that both studied SGADs do not need a fixation tab as the tube has an oval shape bite block which sits between the upper and lower teeth (to ensure it is comfortably secured between the teeth), preventing it from turning over its axis.

Manufacturers of both LMAs produce sizes 4 and 5 with identical cuff dimensions, but the length of bite block differs [11]. Authors would advise manufacturers to withdraw size 4, which would then permit clinicians to use size 5 in most adults.

Manufacturers of SGADs may be confronted with the demand for a shorter stem allowing the device to be used as an intubation conduit in case a tracheal tube needs to be placed urgently. The authors also opine that a longer stem of SGAD may risk dislocation of the tracheal tube during its insertion through the SGAD. During the designing process of SGADs, the manufacturers usually consider adequate length of SGAD tube which may allow a tight apposition between the cuffed SGAD and glottis (first seal, allowing good ventilation of airway) and a tight apposition to the oesophageal opening (second seal), which may prevent reflux and aspiration of gastric content. In case the SGAD needs to be used as an intubation conduit, dislocation of the tube may be prevented by use of longer exchange bougies.

Authors are aware of one pilot study and three other case series where LMA-P was used [19–22]. The pilot study involved 29 Asian gynaecological patients undergoing minor operations, breathing spontaneously through a size 3 LMA-P, resulting in a fast insertion of LMA (median time 19 s), an 88.5% first-attempt insertion success rate, adequate OLPs (median 25.5 cmH_2O), correct positioning of device using fibreoptic inspection (vocal cords visualized in all subjects), and a postoperative sore throat incidence of 23.1%. Sng et al. [19] only used size 3 LMAs and checked position fibreoptically, thus malpositions may not have been detected adequately. Manufacturer's guidelines were followed and sizes 4 and 5 were used in most adults in our study, which revealed optimal SGAD positions, with a smaller incidence of sore throat (12%) and a higher mean OLPs (LMA-S 27.7 cm H_2O; LMA-P 31.7 cm H_2O), the latter much higher than the OLPs obtained by others [23, 24].

This study further shows that LMA-P, successor of LMA-S, offers several advantages in airway management: (a) an all-silicone SGAD does not show proximal cuff folds which are often seen with the PVC version (LMA-P 2% vs. LMA-S 90%) the latter often resulting in leaks as the device does not follow contours of the epiglottis; (b) better anatomical configuration to the patient's airway due to the flexible silicone LMA-P tube (rigid PVC LMA-S tube lacks flexibility which may fail to adjust to patient's anatomy of oropharynx); (c) significant increase in mean OLP, which is the gold standard to create a greater barrier to gastric aspiration; and (d) less need for a different size SGAD.

Limitations of this study included: (a) one anaesthetist inserted and checked the position of all SGADs, which may lack generalisability; (b) LMA-P is a bulkier SGAD, hence, insertion and evaluation may be more difficult in patients with limited mouth openings; (c) muscle relaxants were not used in this study, which may influence device insertion and positioning; (d) vision-guided technique may be valuable at the time of insertion of a SGAD, but does not guarantee optimal position during the maintenance of anaesthesia as the position of the epiglottis can change due to inadvertent movement of patient's head or when one pulls on the SGAD tube; (e) the Caucasian study sample may not be generalisable to other populations; (f) other methods available to further evaluate SGAD positioning were not used (checking the position of the gastric channel, using negative pressure suction, using the passage of a gastric tube via female port or visualization of the oesophagus); and (f) study lacks blind comparison (the study was an open-label trial hence blinding was not possible).

5 Conclusions

The silicone-made LMA-Protector is more flexible and provides higher oropharyngeal leak pressures than the rigid PVC LMA-Supreme. The novel vision-guided 'insert-detect-correct-as-you-go' technique of adequately-sized and anatomically correctly-positioned SGADs, promotes the creation of a safe and effective patient airway and reduces the incidence of suboptimal placement thus avoids the need for further fibreoptic evaluation.

Acknowledgements The authors thank our research nurses Heather Reynolds, Simon Holz, Molly Clarris and Lizanne Dalgleish for their expert assistance in this study.

Funding This study was supported by departmental resources from the Royal Brisbane and Women's Hospital, The University of Queensland, Brisbane, QLD, Australia only.

Compliance with ethical standards

Conflict of interest On behalf of all authors, the corresponding author states that there are no competing interests.

Ethical approval The Royal Brisbane and Women's Hospital Human Research Ethics Committee (HREC/15/QRBW/248, Chairperson Dr. Conor Brophy, dd 03.07.2015) approved the study. This study was registered with the Australia and New Zealand Clinical Trial Registry (ACTRN12615000783527).

Informed consent Written patient's informed consent was obtained from all participants.

References

1. Cook T, Woodall N, Frerk C. 4th National Audit Project of The Royal College of Anaesthetists and The Difficult Airway Society. Major complications of airway management in the United Kingdom. Report and findings. March 2011. ISBN 978-1-9000936-03-3. London: Royal College of Anaesthetists. https://www.rcoa.ac.uk/system/files/CSQ-NAP4-Full.pdf. Accessed 14 Feb 2018.
2. Shorten GD, Opie NJ, Graziotti P, Morris I, Khangure M. Assessment of upper airway anatomy in awake sedated and anaesthetized patients using magnetic resonance imaging. Anaesth Intensive Care. 1994;22:165–9.
3. Brimacombe JR. Laryngeal mask anesthesia—principles and practice, 2nd ed. Philadelphia:Saunders; 2005, pp. 97–99.
4. Aoyama K, Takenaka I, Sata T, Shigematsu A. The triple airway manoeuvre for insertion of the laryngeal mask airway in paralyzed patients. Can J Anaesth. 1995;42:1010–6.
5. Moustafa MA, Abdelhady MM. Fiberoptic assessment of the laryngeal mask airway (LarySeal) position after one hour of positive pressure ventilation: an observational study. J Clin Anesth. 2014;26:480–4.
6. Joshi S, Sciacca RR, Solanki DR, Young WL, Mathru MM. A prospective evaluation of clinical tests for placement of laryngeal mask airways. Anesthesiology. 1998;89:1141–6.
7. Payne J. The use of the fibreoptic laryngoscope to confirm the position of the laryngeal mask. Anaesthesia. 1989;44:865.
8. Van Zundert AAJ, Kumar CM, van Zundert TCRV. Malpositioning of supraglottic airway devices: preventive and corrective strategies. Br J Anaesth. 2016;116:579–82. https://doi.org/10.1093/bja/aew104.
9. Van Zundert AAJ, Gatt SP, Kumar CM, van Zundert TCRV. Vision-guided placement of supraglottic airway device prevents airway obstruction: a prospective study. Br J Anaesth. 2017;118:462–3. https://doi.org/10.1093/bja/aex010.
10. Van Zundert AAJ, Gatt SP, Kumar CM, van Zundert TCRV, Pandit JJ. 'Failed supraglottic airway': an algorithm for suboptimally placed supraglottic airway devices based on videolaryngoscopy. Br J Anaesth. 2017;118:645–9. https://doi.org/10.1093/bja/aex093.
11. Van Zundert AAJ, Skinner MW, van Zundert TCRV, Luney SR, Pandit JJ. Value of knowing physical characteristics of the airway before using it. Br J Anaesth. 2016;117:12–6. https://doi.org/10.1093/bja/aew106.
12. Maitra S, Baidya DK, Bhattacharjee S, Khanna P. Laryngeal mask airway ProSeal provides higher oropharyngeal leak pressure than i-gel in adult patients under general anesthesia: a meta-analysis. J Clin Anesth. 2016;33:298–305. https://doi.org/10.1016/j.jclinane.2016.04.020.
13. Keller C, Brimacombe JR, Keller K, Morris R. Comparison of four methods for assessing airway sealing pressure with the laryngeal mask airway in adult patients. Br J Anaesth. 1999;82:286–7.
14. Seet E. Safety and efficacy of laryngeal mask airway Supreme versus laryngeal mask airway ProSeal: a randomized controlled trial. Eur J Anaesthesiol. 2010;27:602–7. https://doi.org/10.1097/EJA.0b013e32833679e3.
15. Van Zundert AAJ, Wyssusek KH. Only with an optimal position of the supraglottic airway in situ, valid conclusions can be drawn about oropharyngeal airway pressure. Ind J Anaesth. 2018;62:241–2. https://doi.org/10.4103/ija.IJA_135_18.
16. Van Zundert TC, Hagberg CA, Cattano D. Standardization of extraglottic airway devices, is it time yet? Anesth Analg. 2013;117:750–2. https://doi.org/10.1213/ANE.0b013e31829f368b.
17. Levitan RM, Ochroch EA, Kush S, Shofer FS, Hollander JE. Assessment of airway visualization: validation of the percentage of glottic opening (POGO) scale. Acad Emerg Med. 1998;5:919–3. https://doi.org/10.1111/j.1553-2712.1998.tb02823.x.
18. Krage R, van Rijn C, van Groeningen D, Loer SA, Schwarte LA, Schober P. Cormack–Lehane classification revisited. Br J Anaesth. 2010;105:220–7. https://doi.org/10.1093/bja/aeq136.
19. Sng BL, Ithnin FB, Mathur D, Lew E, Han N-LR, Sia AT-H. A preliminary assessment of the LMA Protector™ in non-paralysed patients. BMC Anesthesiol. 2017;17:26. https://doi.org/10.1186/s12871-017-0323-5.
20. Tan LZ, Tan DJ, Seet E. Use of the laryngeal mask airway (LMA) Protector for shoulder surgeries in beach-chair position: a case series. J Clin Anesth. 2017;39:110–11. https://doi.org/10.1016/j.jclinane.2017.03.036.
21. Tan LZ, Tan DJA, Seet E. Laryngeal mask airway protector™: Advanced uses for laparoscopic cholecystectomies. Indian J Anaesth. 2017;61:673–5. https://doi.org/10.4103/ija.IJA_240_17.
22. Tan LZ, Tan DJA, Seet E. Laryngeal mask airway protector™ for intubation and extubation in thyroid surgeries: a case report. Indian J Anaesth. 2018;62:545–8. https://doi.org/10.4103/ija.IJA_43_18
23. Kim MH, Lee JH, Choi YS, Park S, Shin S. Comparison of the laryngeal mask airway supreme and the i-gel in paralysed elderly patients. A randomised controlled trial. Eur J Anaesthesiol. 2018;35:598–604. https://doi.org/10.1097/EJA.0000000000000700.

24. Chaw SH, Shariffuddin II, Foo LL, Lee PK, Pran RM, Cheang PC, Chan L. Comparison of clinical performance of size 1.5 Supreme™ LMA and Proseal™ LMA among Asian children: a randomized controlled trial. J Clin Mon Comput. 2018. https://doi.org/10.1007/s10877-018-0109-4.