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Oesophageal seal of the novel supralaryngeal airway device I-Gel™ in comparison with the laryngeal mask airways Classic™ and ProSeal™ using a cadaver model

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Background. Supraglottic airway devices are increasingly used in anaesthesia and emergency medicine. This study was designed to investigate the oesophageal seal of the novel supralaryngeal airway device, I-Gel™ (I-Gel), in comparison with two of the laryngeal mask airways, Classic™ (cLMA) and ProSeal™ (pLMA), in a model of elevated oesophageal pressure.

Methods. The three supralaryngeal airway devices were inserted into eight unfixed cadaver models with exposed oesophagi that had been connected to a water column producing both a slow and a fast oesophageal pressure increase. The pressure applied until the loss of oesophageal seal during a slow and fast pressure increase was measured.

Results. During the slow increase of pressure, the pLMA withstood an oesophageal pressure up to a median of 58 cm H_2O, while the cLMA was able to block the oesophagus up to a median of 37 cm H_2O, and I-Gel already lost its seal at 13 cm H_2O. One minute after maximum pressure had been applied, the pLMA withstood an oesophageal pressure of 59 cm H_2O, the cLMA of 46 cm H_2O, and I-Gel airway of 21 cm H_2O. A fast release of oesophageal fluid was accomplished through the oesophageal lumen of both the pLMA and I-Gel.

Conclusions. Both the pLMA and cLMA provided a better seal of the oesophagus than the novel I-Gel airway. The pLMA and I-Gel drain off gastrointestinal fluid fast through the oesophageal lumen. Thus, tracheal aspiration may be prevented with their use. Further study is necessary.

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Supralaryngeal airway devices are increasingly used in patients who are traditionally assumed to be at an increased risk for aspiration. In addition to the use for planned anaesthesia,[1] current guidelines also recommend supralaryngeal airway devices as an alternative to tracheal intubation during cardiopulmonal resuscitation.[2] Currently, the classical supralaryngeal airway devices have been refined and various alternatives have been introduced into clinical practice. One of them is the novel I-Gel™ airway device (I-Gel; Intersurgical, Berkshire, UK) which, in contrast to the classical laryngeal mask airway, is equipped with a gel-like cuff made of thermoplastic elastomer. It seals the laryngo-pharyngeal space without any air being insufflated and additionally has an oesophageal lumen.[3] Using a cadaver model, our group showed that there are some major differences between the individual supralaryngeal airway devices regarding sealing capabilities during simulated oesophageal pressure increases.[4] It can be assumed that airway devices that offer an especially good seal and that are equipped with an additional oesophageal lumen are superior for use in patients with an increased risk of aspiration. As the cuff which is relevant to seal was modified during the development of the I-Gel airway device, this study was designed

to investigate oesophageal seal of the I-Gel, as compared with the two laryngeal mask airways LMA Classic™ (cLMA; LMA, Windhagen, Germany) and LMA ProSeal™ (pLMA; LMA, Windhagen, Germany) using a cadaver model.

Methods

Cadaver model

The study was approved by the ethical committee of Charité, Universitätsmedizin, Berlin.

Tracheas and oesophagi of eight unfixed human cadavers (head–neck preparations) were dissected. The distal end of the exposed oesophagi was connected to a vertical flexible hose with a diameter of 2 cm, using a tight suture. By filling the flexible hose with water, an oesophageal pressure increase was simulated. The trachea was connected to a test lung for respirators (Dräger, Lübeck, Germany).

See Table 1 for age, sex, height, and weight of the donors.

The laryngeal mask airways such as cLMA, pLMA, and I-Gel airway were inserted by the same experienced anaesthetist (>1000 laryngeal mask uses) with the cuffs of cLMA and pLMA being blocked in accordance with the manufacturer's instructions (size 4: 30 ml/size 5: 40 ml). The inspiration pressure was measured using a manometer (Dräger, Lübeck, Germany). Subsequently, a functional check of the anatomical position was performed. A pressure of 20 mbar was applied through a respiration bag. A correct position was postulated when no air leak escaped during this manoeuvre and the pressure was maintained. When this did not occur, the position was corrected until the required conditions were met. Additionally, the correct position was checked through the respiratory lumen by means of fibreoptic pharyngoscopy (Brochoscope BF Type 1T40, Olympus, Tokyo, Japan). The position was evaluated according to per cent of glottic opening (POGO) scale:[5] 1, glottis fully visible; 2, >50% of glottis visible; 3, <50% of glottis visible; 4, glottis not visible. As a last step, the correct position of the oesophageal point of the pLMA and I-Gel was verified by inserting a gastric tube through the oesophageal lumen and moving it forward until it became visible at the oesophagi end. For the duration of the tests, the respective airway device was fastened to the face. To prevent the cadaver models from cooling, the tests were carried out at a room temperature of 32°C, with the water of the water column being heated to a temperature of 37°C.

Investigation of the oesophageal seal

Test 1: slow increase of oesophageal pressure

After placing the airway device, a water column was generated by slowly filling the flexible hose connected vertically to the oesophagus. The pressure was increased by filling an additional 5 cm of water every 10 s to a maximum level of 130 cm H_2O. Loss of seal was defined as the pressure at which the column height ceased to increase, with fluid being detected in the lumen of the airway device by fibreoptic means at the same time.

Test 2: fast increase of oesophageal pressure (simulated vomiting procedure)

The water column was filled up to 130 cm H_2O while the lower end of the flexible hose connected to the oesophagus was clamped. The clamp was opened so that immediately after removing the clamp, an oesophageal pressure of 130 cm H_2O was applied to the cuff, gel pad or both of the airway devices. In case of a leakage, the water column decreased correspondingly. The level of the water column 1 min after removing the clamp was registered as the seal. This test was conducted using the pLMA and I-Gel, both with the oesophageal drainage lumen open and closed.

Tests 1 and 2 were conducted 10 times for every airway device in each cadaver model in a randomized order, using random numbers produced by a statistical software (Microsoft Excel). For statistical analysis, the median of the respective series of tests was used.

Table 1 Outline of sex, age, height, weight, and fiberoptic POGO score (per cent of glottic opening) of the eight cadaver models including the required sizes of the airways. Fiberoptic score: 1, glottis fully visible; 2, >50% of glottis visible; 3, <50% of glottis visible; 4, glottis not visible; pLMA, laryngeal mask airway LMA ProSeal™; cLMA, laryngeal mask airway LMA Classic™

Cadaver model	Sex	Age (yr)	Height (cm)	Weight (kg)	POGO score			Size		
					cLMA	pLMA	I-Gel	cLMA	pLMA	I-Gel
1	Female	84	162	84	1	1	1	5	5	4
2	Female	78	158	60	1	1	1	4	4	4
3	Male	78	164	68	1	1	2	4	4	4
4	Male	67	171	84	1	1	1	5	5	4
5	Female	78	164	70	1	1	1	4	4	4
6	Female	82	160	69	1	1	1	4	4	4
7	Male	73	169	73	3	2	3	4	4	4
8	Female	78	174	100	2	1	2	5	5	4

Statistics

The data were checked for normal distribution using the Kolmogorov–Smirnov test before being checked for significant differences in more than two independent samples using the Kruskal–Wallis test. Using the Mann–Whitney *U*-test, a *post hoc* analysis was conducted in which the I-Gel was compared with the cLMA and pLMA, and the cLMA was compared with the pLMA. $P<0.05$ was considered as significant. All statistic procedures were conducted using SPSS™ 10.0 (SPSS, Chicago, IL, USA). If not otherwise stated, data are given in median (25th percentile; 75th percentile).

Results

Insertion and check of correct position

All three supralaryngeal airway devices could be inserted into all eight cadaver models as described earlier. As a result of the functional check for the correct position, both cLMA and pLMA had to be placed again in one case each, whereas the I-Gel had to be placed again in two patients. After that, the functional check could be conducted successfully in all patients. The results of the tests conducted using fibreoptic technique are shown in Table 1.

The Kruskal–Wallis test revealed significant differences for both tests 1 and 2.

Test 1: slow increase of oesophageal pressure

During the slow increase of pressure, the pLMA withstood an oesophageal pressure to a median of 58 cm H_2O (32; 64), while the cLMA was able to block the oesophagus only up to a median of 37 cm H_2O (25; 43), and the I-Gel already lost its seal at a median of 13 cm H_2O (12; 22). In the *post hoc* analysis, a significant difference could be noticed between cLMA *vs* I-Gel ($P<0.001$), pLMA *vs* I-Gel ($P<0.001$), and cLMA *vs* pLMA ($P=0.001$) (Fig. 1).

Test 2: fast increase of oesophageal pressure (simulated vomiting procedure)

One minute after opening the clamp, there was a resulting water column of 59 (55; 61) cm H_2O for the pLMA, of 46 (36; 50) cm H_2O for cLMA, and of 21 (16; 26) cm H_2O for I-Gel airway (Fig. 2). In the *post hoc* analysis, a significant difference could be noticed between the cLMA and the I-Gel ($P=0.003$) and between the pLMA and the I-Gel ($P=0.001$). The difference between the pLMA and the cLMA did not reach significance ($P=0.13$) During Test 2 with the oesophageal lumen of the pLMA and the I-Gel opened, the entire oesophageal liquid was drained to the outside without any tracheal aspiration occurring.

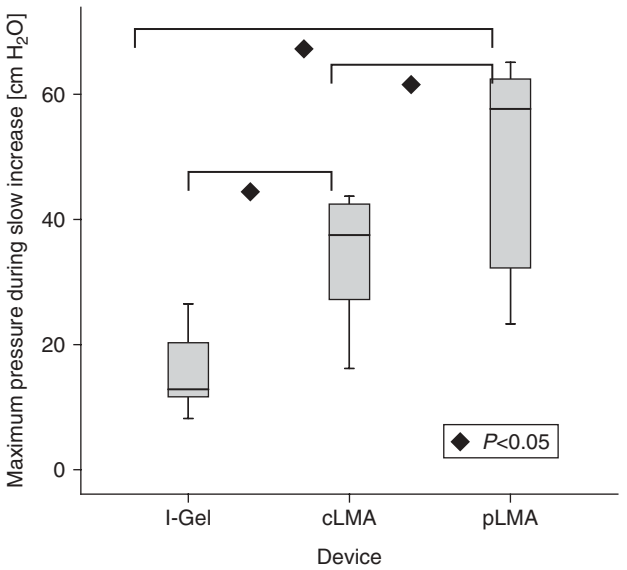

Fig 1 Results of Test 1. The maximum oesophageal pressures achieved during a slow pressure increase before the occurrence of a leakage are depicted as a box plot indicating the median, 5, 25, 75, and 95% quantiles for the LMA Classic™ (cLMA), ProSeal™ (pLMA), and I-Gel airway.

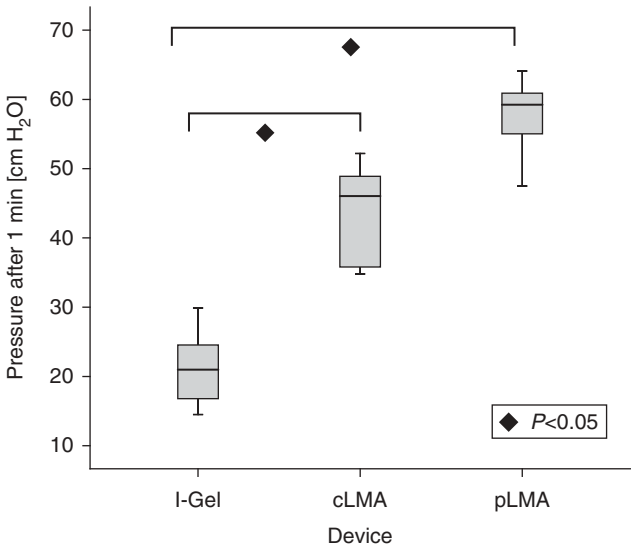

Fig 2 Results of Test 2. The oesophageal pressures remaining 1 min after maximum pressure had been applied to LMA Classic™ (cLMA), ProSeal™ (pLMA) and I-Gel airway are depicted as a box plot indicating the median, 5, 25, 75, and 95% quantiles.

Discussion

This study was performed to investigate the oesophageal seal of the novel airway device I-Gel in comparison with the established laryngeal mask airways cLMA and pLMA. Our results demonstrate that the cLMA and pLMA can withstand a significantly higher oesophageal pressure than the I-Gel airway when using a cadaver model. Independent of this finding, the pLMA and the I-Gel

permitted a fast and complete drainage of oesophageal fluid through their open oesophageal lumens.

The assessment of the risk of aspiration when using supralaryngeal airway devices is impeded by methodological problems. Aspiration during elective operations generally occurs very rarely so that the definite risk of different procedures cannot be precisely evaluated in clinical studies. As the risk of aspiration seems to be increased in pre-hospital use, the problem has been mainly addressed during pre-hospital investigations. Tanigawa and colleagues,[6] for example, detected six cases of aspiration in 2701 resuscitations conducted using the cLMA. Apart from an at least theoretically reduced protection that supralaryngeal airway devices provide when compared with tracheal intubation, they offer advantages such as the fact that they are easier to handle and learning how to use them is easier, as a result of which their use also in pre-hospital settings continues to be evaluated.

Concerning the risk of aspiration, the use of the laryngeal mask airway seems to be superior at least to the classical mask ventilation. Stone and colleagues[7] described a significant difference in terms of clinically relevant aspirations that occurred when using a laryngeal mask airway compared with bag valve mask ventilation (3.5% *vs* 12.4%).[7] Moreover, several case reports on vomiting, regurgitation, or both during the use of supralaryngeal airway devices have been published. The use of airway devices equipped with an additional oesophageal lumen often prevents tracheal aspiration of gastric contents.[8–11]

The difficulties described that occurred when assessing the risk of aspiration led to an evaluation of the risk of aspiration and the seal of supralaryngeal airway devices using cadaver models. By means of the cadaver model presented here, our group could show significant differences in sealing properties of supralaryngeal airway devices (cLMA, pLMA, Intubating Laryngeal Mask Airway Fastrach™, Laryngeal Tube™, Laryngeal Tube LTS II™, Combitube™, and Easytube™). The Combitube™, Easytube™, and Intubating Laryngeal Mask Airway Fastrach™ provided the most effective seal against oesophageal pressures up to 130 cm H_2O. The results obtained by the cLMA and pLMA yielded in this context were similar to those in the present study.[4] During other investigations using cadaver models in which the oesophageal pressure was continuously increased using not a water column but a pump, comparable differences could also be described for the cLMA and pLMA.[12 13] To the best of our knowledge, systematic investigation of the sealing efficiency with the I-Gel airway device has not been reported yet. Thus far, only a case series has been published describing the two cases of regurgitation with successful drainage through the oesophageal lumen and one aspiration with insufficient drainage out of a total of 280 patients.[14] This clinical experience regarding risk of aspiration by lacking, inadequate, or both oesophageal drainage corresponds to our findings.

As this is an experimental study, some limitations have to be taken into consideration when evaluating the results achieved. Unfixed human cadavers were used that do represent patient anatomy exactly, but cannot carry out possible swallowing and retching movements or respond to influences associated with respiration. The fact that some supralaryngeal airway devices are made of thermoplastic material may affect the study results because possible thermoplastic features that occur under the physiological body temperature are usually not considered appropriately. To avoid any distortion, measures were taken to prevent the cadaver models from cooling. The good seal of the larynx during ventilation in all cadavers may be an indication of the fact that the properties of the materials used apparently were not significantly affected by the test conditions. Although the design of the test is suited for making statements about the seal at clearly elevated oesophageal pressures, general recommendations for clinical use cannot be deduced from a cadaver setting.

To carry out the tests both with the oesophageal lumen open and closed in our view was useful. The lumens that are very narrow in both devices can easily be closed by viscous or solid gastric contents. Furthermore, the oesophageal seal can only be investigated with increased oesophageal pressures that could not be achieved with drainage through an open lumen.

Our results suggest that at elevated pressures, the oesophageal seal provided by the cuff of the laryngeal mask airway is superior to the oesophageal seal created by the pre-shaped plastic mask body of I-Gel airway. A possible reason might be that the forces that are responsible for the stabilization of supralaryngeal airway devices within the pharynx are different between I-Gel and cLMA and pLMA. These forces are described only for laryngeal mask airways thus far.[15] However, an optimal position of the airway device was the pre-requisite for conducting this investigation. Possibly, undesired changes of position after the insertion might be less likely using the I-Gel because of its special shape and the fact that no insufflation is required.[16] Additionally, our data suggest that when using the cadaver model ventilation that can be carried out well without any air leak is not necessarily a guarantor of a proper oesophageal seal. Apart from sealing, the safe and efficient use of supralaryngeal airway devices, especially in an emergency setting, may also depend on the ease of use, speed of insertion, the training and practice required, and also possible side-effects.[17–21]

In principal, supralaryngeal airway devices do not prevent aspiration as reliably as tracheal intubation does. Particularly in patients with an increased risk of aspiration, it should be carefully considered whether or not a supralaryngeal airway device is indicated. If the use of supralaryngeal airway device in these conditions is necessary, a device that is equipped with an inflatable cuff and an oesophageal lumen would be most suitable.

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