The PAXpress™ is an effective ventilatory device but has an 18% failure rate for flexible lightwand-guided tracheal intubation in anesthetized paralyzed patients

[Le PAXpress™ est un appareil de ventilation efficace, mais présente un taux d'échec de 18 % pour l'intubation trachéale sous guidage lumineux flexible chez les patients anesthésiés paralysés]

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Purpose: The PAXpress™ is a new, single-use, extraglottic airway device. We evaluate: 1) insertion success rates; 2) airway sealing pressure, ventilatory capability and calculated mucosal pressures (*in vitro* minus *in vivo* intracuff pressure) at 30–60 mL cuff inflation volume; 3) the feasibility of lightwand-guided tracheal intubation; and 4) the incidence of mucosal trauma.

Methods: Ninety anesthetized, paralyzed adults were studied. Airway management was by senior anesthesiologists with no prior experience with the PAX, but considerable experience with extraglottic airway devices and the flexible-lightwand.

Results: Insertion was successful at the first attempt in 95.5% (86/90) and at the second attempt in 4.5% (4/90). Mean $\pm$ SD airway sealing pressure at 30, 40, 50 and 60 mL cuff inflation volume was 27 ± 8 , 29 ± 9 , 32 ± 9 and 35 ± 7 cm H₂O respectively; expired tidal volume at airway sealing pressure was 16 ± 6 , 18 ± 6 , 19 ± 5 and 19 ± 6 mL·kg⁻¹; and calculated mucosal pressure was 38 ± 14 , 55 ± 20 , 56 ± 19 and 57 ± 20 cm H₂O. Airway sealing pressure, expired tidal volume at airway sealing pressure and calculated mucosal pressures increased with cuff inflation volume (all: $P \leq 0.0002$). Esophageal leak was detected in 9% (8/90), but only at peak pressures ≥ 35 cm H₂O and cuff inflation volumes ≥ 40 mL. Lightwand-guided intubation was successful in 82% (74/90) of patients. Mild, moderate and severe blood staining was detected in 40% (36/90), 15% (13/90) and 1% (1/90) respectively. Blood staining was more frequent after adjusting maneuvers (22/54 vs 32/36, $P = 0.002$).

Conclusion: The PAX has a high insertion success rate and is an effective ventilatory device with a low risk of gastric insufflation, but has a moderately high failure rate for lightwand-guided intubation

and is associated with a relatively high incidence of mucosal trauma. Mucosal pressures may exceed pharyngeal perfusion pressure.

Objectif : Le PAXpress™ est un nouvel appareil d'intubation extraglottique jetable. Nous évaluons : 1) le taux de succès de l'insertion ; 2) la pression d'étanchéité dans les voies aériennes, la capacité ventilatoire et les pressions sur la muqueuse calculées (pressions intra-ballonnet *in vitro* moins *in vivo*) pour des volumes du ballonnet de 30–60 mL ; 3) la faisabilité de l'intubation trachéale sous guidage lumineux et 4) l'incidence de traumatisme à la muqueuse.

Méthode : L'étude comportait 90 patients adultes, anesthésiés et paralysés. L'assistance respiratoire a été assurée par des anesthésiologistes qui ne s'était jamais servi du PAX, mais souvent des appareils d'intubation extraglottiques et du stylet lumineux flexible.

Résultats : L'insertion a été réussie au premier essai chez 95,5 % (86/90) et au second chez 4,5 % (4/90) des patients. La moyenne $\pm$ l'écart type de la pression d'étanchéité pour un volume du ballonnet de 30, 40, 50 et 60 mL, a été respectivement de 27 ± 8 , 29 ± 9 , 32 ± 9 et 35 ± 7 cm de H₂O ; le volume courant expiré sous la pression d'étanchéité a été de 16 ± 6 , 18 ± 6 , 19 ± 5 et 19 ± 6 mL·kg⁻¹ ; la pression sur la muqueuse calculée a été de 38 ± 14 , 55 ± 20 , 56 ± 19 et 57 ± 20 cm de H₂O. La pression d'étanchéité, le volume courant expiré sous cette pression et les pressions sur la muqueuse calculées ont augmenté en fonction du volume du ballonnet (tous : $P \leq 0,0002$). Une fuite œsophagienne a été détectée chez 9 % (8/90), mais seulement pour des pics de pression ≥ 35 cm de H₂O et des volumes de ballonnet

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≥ 40 mL. L'intubation sous guidage lumineux a été réussie chez 82 % (74/90) des patients. La présence de sang, bénigne, modérée et sévère, a été détectée respectivement chez 40 % (36/90), 15 % (13/90) et 1 % (1/90). On a détecté du sang plus souvent après les manœuvres d'ajustement (22/54 vs 32/36, $P = 0,002$).

Conclusion : Le PAX présente un taux élevé d'insertion réussie. C'est un appareil ventilatoire à faible risque d'insufflation gastrique, mais il affiche un taux d'échec modérément élevé pour l'intubation sous guidage lumineux et est associé à une incidence relativement importante de traumatisme de la muqueuse. Les pressions sur la muqueuse peuvent dépasser la pression de perfusion.

THE PAXpress™ (PAX; Vital Signs Inc., NJ, USA) is a new extraglottic airway device that is intended to function as a ventilatory device or airway intubator for anesthesia or cardiopulmonary resuscitation (Figure). It was invented by Douglas R. Mongeon of Orange Park Acres, California (US Patent Number: 6,390,093). It is similar to the laryngeal tube airway¹ and airway management device,² but has a gilled distal cuff and is disposable. In this preliminary study, we evaluate: 1) insertion success rates; 2) airway sealing pressure, ventilatory capability and calculated mucosal pressures at 30–60 mL cuff inflation volume; 3) the feasibility of lightwand-guided tracheal intubation; and 4) the incidence of mucosal trauma.

Device description and insertion technique

The PAX is made from PVC and is single-use. It comprises an anatomically curved tube with an inflatable circular cuff in the mid-section that forms a seal in the proximal pharynx for ventilation, and a non-inflatable gilled conical tip at the distal end that forms a no-pressure seal in the hypopharynx for prevention of regurgitation and gastric insufflation. Between the cuff and tip on the inner curve is a rectangular vent that faces anteriorly towards the glottic inlet. The distal half of the vent has three vertical gills to prevent airway obstruction. The internal diameter of the airway tube is 12.3-mm and can accommodate an 8-mm cuffed tracheal tube. The pilot balloon is integral to the airway tube to prevent damage. The maximum recommended cuff inflation volume is 60 mL. There is one size for adults, but a range of sizes is planned. The deflated, lubricated PAX is held in the dominant hand like a pen. The mouth is opened (either with the non-dominant hand, a laryngoscope or by an assistant) and the PAX is advanced into the pharynx until tactile resistance is felt. The cuff is then inflated until an effective seal is obtained for ventilation or the maximum cuff inflation volume is reached.

Methods

After Ethical Committee approval and written informed consent, 90 consecutive ASA I–II patients scheduled for elective surgery, who required tracheal intubation, were studied. Patients were excluded if they were less than 18 yr, had respiratory tract pathology, were at risk of aspiration, or had an inter-incisor distance < 20 mm. Four senior anesthesiologists who had no prior clinical experience with the PAX, but were experienced with the flexible lightwand-guided intubation via the intubating laryngeal mask airway participated in the study. Pre-study training with the PAX comprised reading the instruction manual and manikin practice. The intracuff pressures were measured *in vitro* at 30–60 mL cuff inflation volume in 10-mL increments.

Anesthetic management was standardized. Monitoring was applied prior to anesthetic induction and included an electrocardiograph, pulse oximeter, gas analyzer, non-invasive blood pressure monitor, peripheral nerve stimulator, tidal volume monitor and airway pressure monitor. Anesthesia was induced with fentanyl $1 \mu\text{g}\cdot\text{kg}^{-1}$ followed by propofol $1.5\text{--}3.0 \text{ mg}\cdot\text{kg}^{-1}$. Maintenance was with sevoflurane 1.5–3% in 100% oxygen. Neuromuscular blockade was achieved with cisatracurium $0.05 \text{ mg}\cdot\text{kg}^{-1}$ and maintained with $0.01 \text{ mg}\cdot\text{kg}^{-1}$ boluses to maintain a train-of-four count less than 1. Patients were ventilated via a face mask for three to five minutes.

The PAX was inserted blindly with the head/neck in the neutral position and with jaw thrust applied. A clear, water-based gel without local anesthetic was used for lubrication. The PAX was connected to a circle anesthesia breathing system and the cuff inflated with air until an effective airway was established or the maximum recommended inflation volume reached (60 mL). The criterion for an effective airway was an expired tidal volume of $\geq 7 \text{ mL}\cdot\text{kg}^{-1}$. If an effective airway could not be established after three insertion attempts, the anesthesiologist was free to manage the airway as clinically indicated. The number of insertion attempts was recorded. A failed attempt was defined as removal of the device from the mouth.

Once an effective airway was obtained, intracuff pressure, airway sealing pressure was determined at 30–60 mL cuff inflation volume in 10-mL increments. Airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of $3 \text{ L}\cdot\text{min}^{-1}$ and noting the airway pressure (maximum allowed was $50 \text{ cm H}_2\text{O}$) at which equilibrium was reached.³ Esophageal leak was detected by listening over the epigastrium with a stethoscope⁴ and the airway pressure at which it occurred was noted.

TABLE Airway sealing pressure, expired tidal volumes at peak airway pressures 10–25 cm H₂O and at airway sealing pressure, and calculated mucosal pressure at 30, 40, 50 and 60 mL intracuff inflation volume

	30 mL	40 mL	Cuff inflation volume 50 mL	60 mL	P
Airway sealing pressure; cm H ₂ O	26.8 ± 8.2	28.9 ± 8.7	32.1 ± 8.6	34.9 ± 6.5	< 0.0001
Expired tidal volume; mL.kg ⁻¹					
- At peak airway pressure					
10 cm H ₂ O	7.6 ± 2.8	8.1 ± 2.7	8.3 ± 2.4	8.4 ± 2.5	0.17 (<i>ns</i>)
15 cm H ₂ O	9.8 ± 3.7	10.2 ± 3.5	10.7 ± 4.1	10.8 ± 3.9	0.26 (<i>ns</i>)
20 cm H ₂ O	12.2 ± 3.9	12.9 ± 4.2	13.5 ± 4.6	13.4 ± 4.1	0.15 (<i>ns</i>)
25 cm H ₂ O	14.1 ± 4.3	15.2 ± 5.1	15.9 ± 4.9	16 ± 4.4	0.025
- At airway sealing pressure	15.6 ± 6.2	17.9 ± 5.8	18.7 ± 5.0	19.1 ± 5.8	0.0002
Calculated mucosal pressure; cm H ₂ O	37.5 ± 13.6	54.5 ± 20.3	55.7 ± 19.4	57.4 ± 20	< 0.0001

Measurements were made with gentle manual positive pressure ventilation. Expired tidal volume was determined at 30–60 mL cuff inflation volume in 10-mL increments with peak airway pressures set at 10–25 cm H₂O in 5-cm H₂O increments. In addition, expired tidal volume was determined with peak pressures set at airway sealing pressure. Measurements were made with the head/neck in the neutral position and the occiput on a firm pillow 7 cm in height.

Once these data were collected, a well-lubricated, straight silicone tracheal tube (Euromedical, Malaysia), preloaded with a prototype flexible lightwand,⁵ was inserted into the PAX and advanced beyond the distal aperture whilst observing the glow in the neck. A size 7.0 or 7.5 mm tracheal tube was used in females and a size 8.0 mm in males. Room lighting was reduced. If a glow could not be seen, the skin over the neck was stretched and/or the neck flexed/head extended to increase the thyrosternal distance. Whenever slight tactile resistance was felt, a variety of adjusting maneuvers were instituted according to the location of the light glow. If the glow was located in the midline, the following adjusting maneuvers were instituted in sequence: A) cuff deflation, withdrawal by 0.5–1.0 cm and cuff reinflation; B) extension of the neck; C) anterior pressure to the front of the neck. If the glow was in the lateral position, the following adjusting maneuvers were instituted in sequence: A) pushing from the side of the glow towards the cricoid cartilage; B) deflating the cuff, twisting the PAX by approximately 45° and simultaneously withdrawing it by 1 cm. When the tube easily advanced 8 cm beyond the distal aperture, the anesthesiologist initiated ventilation. A maximum of three intubation attempts was permitted. Between intubation attempts, the patient was ventilated via the PAX. An intubation attempt through the PAX was defined as a forward and backward movement of the tracheal

tube. The number of attempts at tracheal intubation through the PAX and the depth of the PAX at the incisors after successful intubation were noted. Following successful intubation, the PAX was removed and the quantity of blood staining noted (mild: blood covering < 10% of gills; moderate: 10–20% of gills; and severe: > 20% of gills. Any episodes of hypoxia (SpO₂ < 90%) were noted.

Calculated mucosal pressures were determined by subtracting *in vivo* from *in vitro* intracuff pressures. Statistical analysis was with one-way ANOVA with Bonferroni post hoc test for multiple comparisons paired, Chi-squared test and Fisher's exact test. Significance was taken as $P < 0.05$.

Results

The mean ± SD age, weight and height was 51 ± 17 yr, 73 ± 15 kg and 165 ± 10 cm. The male:female ratio was 34:56. The number of patients managed by each anesthesiologist was 12, 15, 20 and 43. There were no differences in performance among anesthesiologists. PAX insertion was successful at the first attempt in 95.5% (86/90) and at the second attempt in 4.5% (4/90). Airway sealing pressures, expired tidal volumes and calculated mucosal pressures are given in the Table. Airway sealing pressure ($P < 0.0001$), expired tidal volume at airway sealing pressure ($P = 0.0002$) and calculated mucosal pressures ($P < 0.0001$) increased with cuff inflation volume. Expired tidal volume at peak airway pressures 10–20 cm H₂O did not increase with cuff inflation volume, but there was a slight increase at 25 cm H₂O ($P = 0.025$). Expired tidal volume increased with peak airway pressure at all cuff inflation volumes (all: $P < 0.0001$). Esophageal leak was detected in 9% (8/90). The mean (range) airway sealing pressure and cuff inflation volume at which esophageal leak occurred was 37 (35–45) H₂O and 51 (40–60) mL respectively. Lightwand-guided

FIGURE The PAXpress™.

intubation was successful in 82% (74/90) of patients. Of these, 60% (54/90) were intubated at the first attempt without any adjusting maneuvers, 11% (10/90) were intubated at the first attempt with one adjusting maneuver, 6% (5/90) were intubated at the first attempt with two adjusting maneuvers, 2% (2/90) were intubated at the first attempt with three adjusting maneuvers and 4% (3/90) at the second attempt with two or three adjusting maneuvers. Lightwand-guided intubation failed in 18% (16/90) of patients. There were no episodes of esophageal intubation. Mild, moderate and severe blood staining was detected in 40% (36/90), 15% (13/90) and 1% (1/90) respectively. Blood staining was more frequent if adjusting maneuvers were required (22/54 *vs* 32/36, $P = 0.002$). There were no episodes of hypoxia or hypercapnea. The success rate for lightwand-guided intubation increased between the first and last 30 patients (21/30 *vs* 28/30, $P = 0.04$).

Discussion

We found that the PAX was easy to insert with insertion success rates similar to other preliminary studies of extraglottic airway devices such as the Laryngeal Mask Airway Classic™,⁶ the Laryngeal Mask Airway Fastrach™,⁷ the Laryngeal Mask Airway ProSeal™,⁸ the Laryngeal Tube Airway™⁹ and the Cuffed Oropharyngeal Airway™.¹⁰ The efficacy of seal (25–35 cm H₂O) was higher than the cuffed oropharyngeal airway (16–22 cm H₂O)^{11,12} and the classic laryngeal mask airway (17–27 cm H₂O),^{13,14} but similar to the intubating laryngeal mask airway (36–37 cm H₂O),^{15,16} the

ProSeal™ Laryngeal Mask Airway (27–36 cm H₂O)^{8,17} and Laryngeal Tube Airway™ (30 cm H₂O).⁹ We found that inflating the cuff from 30 to 60 mL improved the seal from 26 to 35 cm H₂O. This is similar to the pattern of changing seal with cuff inflation volume found with the laryngeal tube airway.¹⁸

Esophageal leaks occurred in 8.9% of patients and at airway pressures greater than 35 cm H₂O and at high cuff inflation volumes. This suggests that the gills at the distal tip form an effective seal in the hypopharynx and has implications for prevention of gastric insufflation and, possibly, prevention of regurgitation of gastric contents. By contrast, esophageal leaks with the Laryngeal Mask Airway Classic™ occur at 20–30 cm H₂O^{19,20} and with the Cuffed Oropharyngeal Airway™ at probably 10–20 cm H₂O.²¹ Gills have been shown to form an effective seal (> 40 cm H₂O) with the glottis when incorporated into tracheal tube design.²²

We found that flexible lightwand-guided intubation with the PAX had a first attempt insertion success rate without adjusting maneuvers of 60%, a first attempt insertion success rate with adjusting maneuvers of 79% and an overall intubation success rate of 82%. This compares with a first attempt insertion success rate without adjusting maneuvers of 62%, a first attempt insertion success rate with adjusting maneuvers of 92% and overall intubation success rate of 100% for flexible lightwand-guided intubation with the intubating laryngeal mask airway.²³ We found tentative evidence for skill acquisition and speculate the intubation success rates will improve with experience and better understanding of the adjusting maneuvers. To optimize the intubation success rate, we recommend applying jaw thrust during PAX insertion and ensuring that the tube is in the midline and not pulled sideways by the anesthesia breathing system. Other potential options for intubation with the PAX include fiberoptic-guided intubation within and outside the cuff, as described for the Oesophageal Tracheal Combitube™.^{24,25}

We found that calculated mucosal pressures were approximately 40–60 cm H₂O. Pharyngeal mucosal perfusion is progressively reduced when mucosal pressures increase from 34 to 80 cm H₂O²⁶ suggesting that pharyngeal perfusion could potentially be impaired with the PAX. To minimize mucosal ischemic injury, cuff volume should be reduced to the minimum required to form an effective seal. We found that mucosal trauma occurred in 56% of patients. This may be related to the high mucosal pressures, but could also be caused by shearing forces during insertion, adjusting maneuvers and removal since the procedures were of short duration (25–30 min). The high

incidence of trauma associated with adjusting maneuvers suggests that shearing forces are a prime factor in mucosal injury. Interestingly, the incidence of mucosal trauma with the intubating laryngeal mask airway is 23% for lightwand-guided intubation via the intubating laryngeal mask airway²⁷ despite much higher mucosal pressures and similar numbers of adjusting maneuvers.¹⁶ Perhaps shearing injuries are less common with the intubating laryngeal mask airway.

Our study has a number of limitations. First, only one size of PAX was available and it is likely that performance would improve with a wider range since this appears to be the case for other extraglottic airway devices. Second, we did not measure mucosal pressures directly, but rather calculated them from *in vitro* and *in vivo* intracuff pressures. However, it has been shown that intracuff pressures are excellent predictors of directly measured mucosal pressures with the cuffed oropharyngeal airway that has a similar thin-walled cuff to the PAX.²⁶ Third, although we demonstrated relatively high mucosal pressures and a high incidence of mucosal trauma, this does not necessarily equate to a higher incidence of postoperative airway morbidity.

We conclude that the PAX has a high insertion success rate and is an effective ventilatory device with a low risk of gastric insufflation, but has a moderately high failure rate for lightwand-guided intubation and is associated with a relatively high incidence of mucosal trauma. Mucosal pressures may exceed pharyngeal perfusion pressure.

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