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RESEARCH PAPER

Clinical evaluation of the v-gel supraglottic airway device in comparison with a classical laryngeal mask and endotracheal intubation in cats during spontaneous and controlled mechanical ventilation

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Abstract

Objective To compare airway management during induction of anaesthesia, in spontaneous ventilation and controlled mechanical ventilation (CMV), using a cat-specific supraglottic airway device (the v-gel), a classical laryngeal mask (LM) or an endotracheal tube (ETT).

Study design Prospective, randomized clinical trial.

Animals Forty-five healthy cats.

Methods After premedication, cats were randomly allocated to one of three groups to secure the airway: 1) v-gel; 2) LM; or 3) ETT (cuff pressure: 20 cm H_2O). Cats were anaesthetized for elective procedures. The dose of propofol necessary to insert the v-gel, LM or ETT, the number of attempts required to achieve insertion and leakage during spontaneous ventilation and CMV at different peak inspiratory pressures (8, 10, 12, 14 and 16 cm H_2O) were recorded. Leakage of >20% of tidal volume was considered as a criterion for exclusion. Significance was set at a p-value of <0.05.

Results Cats in the v-gel group required a median (range) of 3 mg kg^{-1} (2–5 mg kg^{-1}) of propofol for successful placement, which was significantly less than the 5 mg kg^{-1} (3–7 mg kg^{-1}) required for endotracheal intubation ($p = 0.005$). No significant difference in the total dose of propofol was observed between the v-gel and LM [3 mg kg^{-1} (2–7 mg kg^{-1})] groups or the ETT and LM groups. Significantly more cats in the ETT group were excluded for leakage of >20% during CMV at all pressure settings.

Conclusions and clinical relevance The v-gel is a practical alternative to the LM and ETT for securing the airway after induction of anaesthesia and for CMV up to 16 cm H_2O in healthy cats. The v-gel can be inserted at a more superficial level of anaesthesia than the ETT and showed significantly less leakage during CMV than the ETT.

Keywords cat, controlled mechanical ventilation, endotracheal tube, laryngeal mask, v-gel.

Introduction

The securing of the upper airway is of major concern during general anaesthesia to ensure patency of the airway and the option to apply controlled mechanical ventilation (CMV). The endotracheal tube (ETT)

is still considered to represent the reference standard method in veterinary practice, but it may be associated with several life-threatening complications in cats, such as soft tissue swelling, arytenoidal tears and even tracheal rupture (Hardie et al. 1999; Lawrence et al. 1999; Mitchell et al. 2000; Hofmeister et al. 2007). Endotracheal intubation is associated with a twofold increase in the odds for death in cats (Brodbelt et al. 2007). The likelihood of these complications can be minimized by using a supraglottic airway device (SGAD) such as a classical laryngeal mask (LM) or a v-gel. Although the LM was developed for human medicine, it has been used successfully in cats (Asai et al. 1998; Cassu et al. 2004); nevertheless, its design does not mirror the oropharyngeal anatomy of cats. The v-gel is a cat-specific SGAD consisting of a non-inflatable cuff that forms a seal around the laryngeal inlet and an inflatable device that can increase seal pressure (Crotaz 2010). In a clinical study, the time from first injection of propofol to the first clinically acceptable reading on the capnograph was significantly shorter in animals in which the v-gel was applied compared with those in which an ETT was used (van Oostrom et al. 2013). In addition, cats receiving an ETT showed significantly more stridor during recovery, although this could not be definitively attributed to ETT use alone.

The aim of this prospective, randomized clinical study was to compare the depth of anaesthesia required and total attempts required to place the v-gel, LM and ETT, respectively, and the occurrence of leakage during spontaneous ventilation and CMV in anaesthetized cats. We hypothesized that the placement of the v-gel would require less propofol and fewer attempts than placement of the LM or ETT. Furthermore, we hypothesized that leakage in the v-gel group would occur at lower and higher pressure settings than with the ETT and LM, respectively.

Materials and methods

This prospective, randomized clinical study was granted ethical approval by the Swiss Federal Ethics Committee of Canton Zurich (198/2012). Randomization was accomplished using an opaque envelope.

Animals and anaesthesia

Forty-five client-owned cats (37 European Shorthair, four Main Coon, two Birman, one British Shorthair, one Burmese), including 15 males and 30 females, weighing a mean ± standard deviation of 3.4 ± 0.8 kg were included.

The cats were found to be healthy upon clinical examination and classified as being of American Society of Anesthesiologists (ASA) class I or II status. Exclusion criteria were body weight of <2 kg, a history of respiratory or upper gastrointestinal problems, a body condition score of >7 out of 9, and treatment with drugs other than non-steroidal anti-inflammatory drugs. Cats were scheduled to undergo general anaesthesia for spaying (29 females), castration (14 males) or other elective surgery (lasering of an iris melanoma, $n = 1$; ureter stent, $n = 1$).

Food, but not water, was withheld for at least 6 hours prior to anaesthesia.

Placement of the airway device

Anaesthesia was always performed by the same anaesthetist (SAP). The anaesthetist remained unaware of the animal's group allocation until an adequate level of anaesthesia for placement of an airway device was reached based on a predefined score (Appendix 1). An intravenous (IV) catheter was placed and an infusion of a crystalloid solution [Ringer-Laktat; Fresenius Kabi (Schweiz) AG, Switzerland] at 5.0 mL kg^{-1} $hour^{-1}$ was started, after which the cat was left undisturbed in a cage for at least 10 minutes. Thereafter, cats were premedicated with methadone 0.1 mg kg^{-1} (Methadon Streuli; Streuli Pharma AG, Switzerland) and diluted medetomidine 5 μg kg^{-1} (Dorbene; Graeub AG, Switzerland) mixed in a syringe filled to 3 mL with sterile saline, given IV slowly over 3 minutes. After another 5 minutes, sedation was assessed using a sedation score (Navarrete et al. 2011) by the anaesthetist (SAP), who was unaware of treatment allocation. The cats were then preoxygenated for another 3 minutes and the following five predefined criteria (Gurney et al. 2009) for adequate level of anaesthesia were assessed with the cat in sternal recumbency: palpebral reflex; jaw tone; protraction of tongue; reaction to touching of the tongue (not epiglottis) with a laryngoscope, and reaction to spraying of the larynx with diluted lidocaine 2% (Kantonsapotheke Zürich, Switzerland). If any of these five criteria were not fulfilled, a 1 mg kg^{-1} bolus of propofol [propofol 1% MCT; Fresenius Kabi (Schweiz) AG] was given over 20 seconds and the criteria reassessed after 20 seconds. Lidocaine spraying was repeated if necessary but a predefined

maximum of 2 mg kg^{-1} was set. Only when all five criteria were fulfilled was the anaesthetist made aware of the predetermined treatment group and the first insertion of the allocated airway device was attempted. Fifteen cats were allocated to each of the v-gel, LM and ETT groups. If this attempt failed because of coughing, retching or gagging, another bolus of propofol of 1 mg kg^{-1} was given over 20 seconds and the next attempt was undertaken after a further 20 seconds. The administration of propofol boli was repeated until the successful placement of the device was possible in sternal recumbency. The total amount of propofol needed and the number of attempts required to place the airway device were recorded.

The v-gel device (sizes C1 to C6; Docsinnovent Ltd, UK) was inserted while the tongue was pulled slightly outward, with the opening of the cuff facing ventrally until the device could not be inserted any further. The device was inserted according to the manufacturer's guidelines (http://docsinnovent.com/downloads/v-gel_Tech_Sheet-med.pdf). The LM (deflated) (Soft Seal Laryngeal Mask; Portex Ltd, UK) was inserted as described for the v-gel. The LM was then inflated (to a volume in line with the guideline indicated on the cuff balloon) to the point at which it moved slightly rostrally to ensure correct placement according to existing guidelines for the use of the LM in dogs (Wiederstein & Moens 2008). Size 1 LMs were used in all cats. The ETT (Mallinckrodt; Covidien, Inc., MA, USA) was inserted with the aid of a laryngoscope and its cuff (low pressure, high volume) was inflated using a pressure gauge to 20 cm H_2O. The ETTs used ranged in size from 3.5 mm to 4.5 mm in internal diameter and were selected according to the hospital's guidelines. All airway devices were secured with a gauze around the neck.

The paediatric airway connector of a spirometer with capnography ($NICO_2$; Respironics, Inc., PA, USA) was placed between the airway device and the Y-piece (internal diameter 12 mm) of the anaesthetic machine (Aespire; Datex Ohmeda, Inc., WI, USA). Anaesthesia was maintained with isoflurane vaporized in an oxygen/air mixture (FiO_2 targeted at 50%) at a flow of 2 L $minute^{-1}$ using a circle rebreathing system and adjusted at the anaesthetist's discretion.

If any cat without a secured airway (not tracheally intubated) showed signs of upper airway obstruction or a pulse oximetry reading of <90% for >60 seconds at any time during the study period, an immediate endotracheal intubation was performed irrespective of the initial allocation and the cat was excluded from further data collection (Fig. 1).

Leakage during spontaneous and controlled mechanical ventilation

When cats were at a stable level of anaesthesia, 10 spontaneous breaths were recorded and thereafter CMV was initiated at a peak inspiratory pressure (PIP) of 8 cm H_2O and increased in increments of 2 cm H_2O to a maximum of 16 cm H_2O.

A minimum of 10 breaths was allowed for each pressure setting. To detect any leakage, the difference between the inspiratory and expiratory tidal volume (TV) in mL was continuously monitored.

If a cat was breathing against the ventilator, the level of anaesthesia was deepened and CMV re-attempted.

If leakage of >20% of TV occurred at a certain pressure setting, the trial was stopped and any cat with an SGAD was endotracheally intubated. After the collection of data at 16 cm H_2O, the study period was considered complete (Fig. 1) and cats proceeded to follow standard protocols for surgical preparation and recovered with appropriate analgesia.

The exact leakage in mL $breath^{-1}$ for each pressure setting was evaluated retrospectively by analysing the inspiratory and expiratory volume using dedicated software (Analysis Plus; Novametrix Medical Systems, Inc., CT, USA).

Statistics

A statistical power analysis (Erdfelder et al. 1996) was performed for sample size estimation to determine the number of animals per group required to detect significant differences in propofol requirement and leakage, respectively. In the first part of this study, this analysis was based on data from a previous study performed in dogs (Wiederstein et al. 2006), which compared propofol requirements for placement of the LM and ETT. In the second part, this analysis was based on assumed pressure settings at which all cats in the three groups would show leakage of 20% of TV. With an alpha value of 0.05 and power of 0.8, projected sample sizes were, respectively, nine and 12 animals per group. We decided to include 15 animals per group to compensate for possible technical problems during data collection.

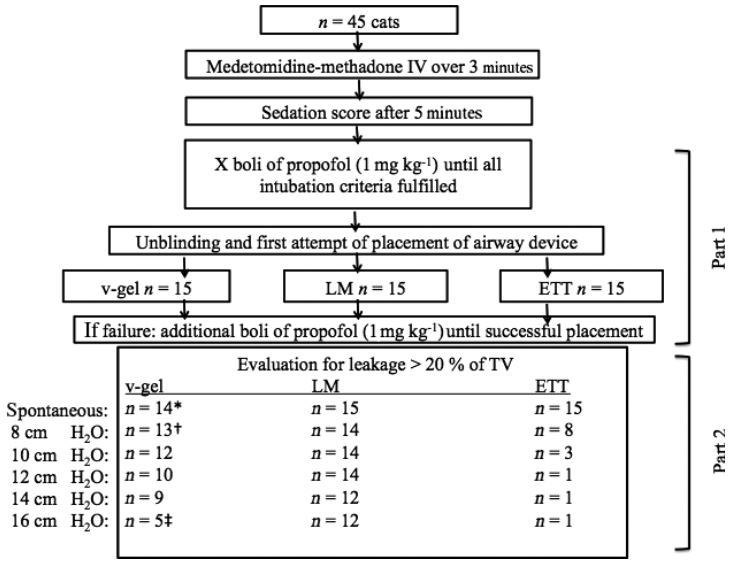

Figure 1 Flow diagram showing the study protocol for investigating the total dose of propofol required for the placement of a v-gel device, laryngeal mask (LM) or endotracheal tube (ETT) and the occurrence of leakage of >20% of tidal volume (TV) with spontaneous and controlled mechanical ventilation (CMV) at 8, 10, 12, 14 and 16 cm H_2O. *One cat in the v-gel group was excluded from the second part of the study as a result of airway problems. †One cat was excluded during CMV because of a decreased pulse oximetry reading. ‡One cat was excluded at 16 cm H_2O for problems with ventilation. IV, intravenous.

All data were analysed using MICROSOFT OFFICE EXCEL 2011 (Microsoft Corp., WA, USA) and IBM SPSS Statistics for Windows Version 21.0 (IBM Corp., NY, USA). Continuous variables were analysed with the non-parametric Kruskal–Wallis test as data were not normally distributed. Discrete variables were analysed using Fisher's test. Differences were considered statistically significant if $p < 0.05$. Data are reported as the median (range).

Results

Forty-five cats were initially included in the study. Demographic data and sedation scores after premedication are shown in Table 1. No statistically significant differences were observed between groups with respect to age, weight, body condition score or sedation score. Dropout rates and time-points are shown in Fig. 1.

Placement of the airway device

Data for all 45 cats were included in this part of the study. The v-gel group required significantly less propofol [3 mg kg^{-1} (2–5)] compared with cats in the ETT group [5 mg kg^{-1} (3–7)]. The median dose of propofol required in the LM group was 3 mg kg^{-1} (2–7). No significant difference in the total dose of propofol emerged between the v-gel and LM groups, or the ETT and LM groups (Fig. 2). In none of the cats was the maximum dose for lidocaine spray during airway device placement reached. Age, weight, body condition scores, total sedation scores and number of attempts did not have any influence on the total dose of propofol. There was no significant difference among the v-gel, LM and ETT groups in the total number of insertions attempted.

Leakage during spontaneous and controlled mechanical ventilation

Twelve of 15 cats in the v-gel group completed this part of the study: one cat showed signs of upper airway obstruction after insertion of the v-gel and evaluation was not possible during spontaneous ventilation; thus the v-gel was removed and the cat excluded. Another cat was excluded at the pressure setting of 8 cm H_2O because of a low pulse oximetry reading (SpO_2 < 90%); this cat underwent immediate endotracheal intubation. A third cat was excluded at the PIP level of 16 cm H_2O because of technical problems with the ventilator (Fig. 1). During spontaneous ventilation, no cat showed leakage of >20% of TV.

There were significant differences regarding the occurrence of leakage of >20% of TV between the

Table 1 Age, body weight, body condition score and total sedation score after premedication in the v-gel, laryngeal mask (LM) and endotracheal tube (ETT) groups. Values are given as the median (range)

Parameter	v-gel	LM	ETT
Age (years)	0.7 (0.5–5.0)	0.7 (0.5–9.0)	0.5 (0.3–5.0)
Weight (kg)	3.1 (2.4–5.3)	3.2 (2.5–5.1)	3.1 (2.3–5.0)
Body condition score (1–9)	5 (3–7)	5 (3–6)	5 (4–6)
Sedation score (0–15)	8 (0–15)	6 (0–12)	11 (1–15)

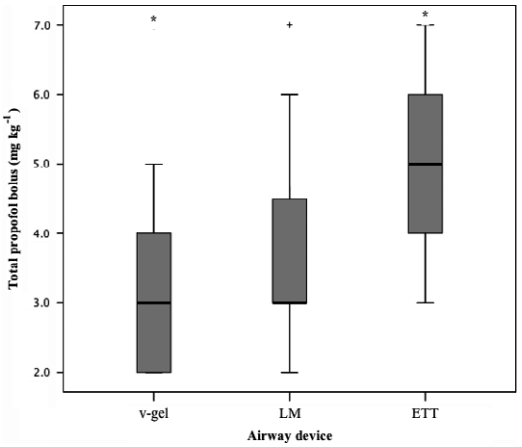

Figure 2 Median and interquartile range of total dose of propofol required for successful insertion of a v-gel device, laryngeal mask (LM) or endotracheal tube (ETT). *Significant difference between the v-gel and ETT groups. †One cat in the LM group required 7 mg kg^{-1} propofol.

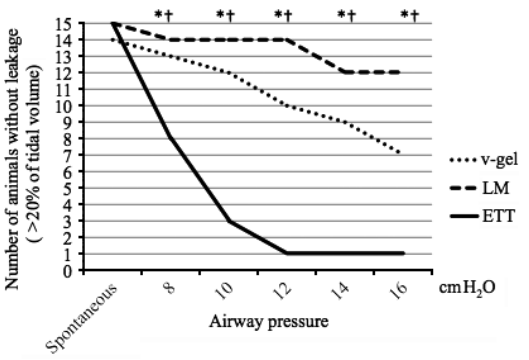

Figure 3 Kaplan–Meier graph showing the numbers of animals without leakage (>20% of tidal volume) during spontaneous and controlled mechanical ventilation at pressure settings of 8, 10, 12, 14 and 16 cm H_2O with the v-gel, laryngeal mask (LM) and endotracheal tube (ETT). *Significant differences between the LM and ETT groups. †Significant differences between the v-gel and ETT groups. There was no significant difference between the v-gel and LM groups at any of the pressure settings. Three cats in the v-gel group were excluded for technical problems other than leakage (see Fig. 1).

v-gel and ETT groups (8 cm H_2O, $p = 0.035$; 10 cm H_2O, $p = 0.001$; 12 cm H_2O, $p = 0.001$; 14 cm H_2O, $p = 0.001$; 16 cm H_2O, $p = 0.001$) and the ETT and LM groups (8 cm H_2O, $p = 0.007$; 10 cm H_2O, $p = 0.001$; 12 cm H_2O, $p = 0.001$; 14 cm H_2O, $p = 0.001$; 16 cm H_2O, $p = 0.001$) at all pressure settings (Fig. 3). The ETT group had significantly more leakage at PIP pressures of >8 cm H_2O than the v-gel and LM groups.

Discussion

One of the main findings of this study is that the total dose of propofol required for placement of a v-gel device was statistically lower than that required for endotracheal intubation. The potentially lower dose of propofol can be advantageous by lowering the incidence of known side effects such as hypoventilation, hypoxemia, apnoea and hypotension (Keegan & Greene 1993; Branson & Gross 1994; Thurmon et al. 1994).

A study in cats showed no difference between the v-gel and ETT regarding the amount of propofol required for insertion of the airway device (van Oostrom et al. 2013). These authors used potentially stronger sedation protocols, resulting in deeper sedation, and larger increments of propofol application and did not assess the depth of anaesthesia. This probably made it difficult to detect smaller differences in propofol requirements between the two groups. Our study design was more sensitive in detecting smaller differences in propofol requirements.

We used lidocaine in all cats in order to have a more comparable starting position, whereas in the study by van Oostrom et al. (2013), only the larynxes of cats in which an ETT was to be inserted were desensitized. This may have led to a lower propofol requirement in the ETT group, thus hiding a real difference between v-gel and ETT insertion.

No significant difference was found between the v-gel and LM regarding the total dose of propofol required for placement. There are no comparable studies in cats or other species that would support our findings. However, our results are not surprising as both devices are SGADs and therefore there is no need to completely abolish airway reflexes as with endotracheal intubation (Cassu et al. 2004).

No significant difference was found in total propofol requirement for placement of an LM and ETT, respectively. This finding contrasts with that in a study performed in cats, in which the level of anaesthesia required for insertion of the ETT was higher than that for the LM (Cassu et al. 2004). A lower dose of induction agent for the insertion of an LM than for an ETT has been shown in other species such as dogs (Wiederstein et al. 2006) and humans (Brain 1985; Blake et al. 1992; Wilkins et al. 1992; Casati et al. 1999). The median dose of propofol in this study was 3 mg kg^{-1} in the LM group and 5 mg kg^{-1} in the ETT group, which suggests that despite the lack of a statistically detectable difference, there was a trend towards a lower propofol requirement in the LM group.

The number of attempts required for insertion did not differ significantly among the v-gel, LM and ETT groups. The placement of the v-gel device caused difficulties in some cats: one cat showed persistent signs of upper airway obstruction, although two different sizes of device were tested. Data for a second cat were excluded after an SpO_2 reading of < 90%; this low measurement was possibly caused by the epiglotic rest of the v-gel leading to reduced blood flow in the tongue. The use of another location for the pulse oximetry probe may circumvent this problem. Choosing a v-gel of appropriate size posed a problem in some cats despite a dedicated guideline. By contrast, an LM of size 1 could be used in all cats in the LM group.

During spontaneous ventilation no leakage was found in any group. This is in agreement with a study in cats that found no clinically significant leakage during spontaneous breathing with a v-gel or ETT (van Oostrom et al. 2013).

The leakage during CMV was comparable in the v-gel and LM groups. By contrast, significantly more animals in the ETT group showed leakage of >20% of TV during CMV compared with those with SGADs. This finding is surprising as we expected the ETT to allow the least amount of leakage as a result of its sealing cuff. One study comparing LM and ETT in cats failed to show any obvious leakage using peak inspiratory pressure up to 13 cm H_2O (Cassu et al. 2004). By contrast with our study, the endotracheal cuff pressures in the study reported by Cassu et al. (2004) ranged from 60 mmHg to 100 mmHg. Inflation of the low-pressure high-volume cuff of the ETT to 20 cm H_2O is known to prevent any mucosal damage of the trachea as a result of compression (Loeser et al. 1978; Seegobin & van Hasselt 1984; Joh et al. 1987), which is why we chose a cuff pressure of 20 cm H_2O. This may have led to the higher incidence of leakage.

In our study, we detected leakage by measuring the difference between inspiratory and expiratory volumes, whereas in other studies leakage was detected by measuring the peak concentration of isoflurane in the vicinity of the mouth or checking for its audibility (Cassu et al. 2004; van Oostrom et al. 2013). We do not consider these methods suitable for the precise quantification of the volume of leakage per breath.

In the LM group, two female cats were diagnosed with bloating of the stomach by the surgeon after opening the abdomen. Bloating was not detected in any other female during laparotomy. However, we cannot exclude the possibility of bloating in the 15 males during CMV. Findings in human medicine have shown there to be an increased risk for gastro-oesophageal reflux and possible aspiration with the use of an LM because of gastric bloating caused by insufficient sealing of the glottis, especially during CMV (Valentine et al. 1994). In the present study, the occurrence of gastric reflux during spontaneous and controlled mechanical ventilation was not investigated. Interestingly, one study in cats found a higher incidence of gastric reflux during CMV using an ETT compared with an LM, without leading to pulmonary aspiration (Cassu et al. 2004). With reference to this possible complication, the manufacturer of the v-gel declares that the tip of the device forms a seal in the oesophagus that prevents the subsequent aspiration of possible gastric reflux (http://docsinnovent.com/downloads/v-gel_Tech_Sheet-med.pdf). Further studies are needed to investigate and verify this issue.

The main limitation of the present study refers to the fact that the positioning of the cat was not changed during the study period. Therefore, we are unable to comment on the displacement of devices during repositioning.

Larger prospective clinical trials will be needed to confirm the benefits and drawbacks described in this

study of the use of the v-gel device for airway management in cats.

In conclusion, the v-gel device seems to be a feasible alternative to the classical LM and ETT for securing the airway after induction of anaesthesia and for CMV up to 16 cm H_2O in healthy cats. Insertion of the v-gel can be achieved at a more superficial level of anaesthesia compared with endotracheal intubation and the device showed significantly less leakage during CMV compared with the ETT.

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Appendix 1

Criteria for assessment of insertion of a v-gel device, laryngeal mask (LM) and endotracheal tube (ETT) (modified from Gurney et al. 2009)

Assessed criteria	Result required to proceed to next criterion
1 Palpebral reflex	Weak
2 Jaw tone	No resistance
3 Protraction of tongue	No resistance/swallowing
4 Laryngoscope on tongue	No swallowing/gagging/retching
5 Lidocaine on larynx	No swallowing/gagging/retching

→ Allocation to v-gel/LM/ETT and first attempt of insertion/intubation in sedation.