British Journal of Anaesthesia **100 (3):** 415–17 (2008)
doi:10.1093/bja/aem396 Advance Access publication January 29, 2008

BJA

Case report

Case series: protection from aspiration and failure of protection from aspiration with the i-gel airway†

B. Gibbison*, T. M. Cook and C. Seller

Royal United Hospital, Combe Park, Bath BA1 3NG, UK
**Corresponding author. E-mail: ben@gibbison.com*

We present three patients of regurgitation while using the i-gel supraglottic airway in 280 patients. In two patients, the i-gel completely protected the airway from aspiration. In one patient, it did not provide complete protection. The i-gel has features designed to separate the airway and gastro-intestinal tracts and as such should offer some protection against aspiration. However, the efficacy of these features has not been confirmed, and further study is required to determine the safety profile of the device.

Br J Anaesth 2008; **100**: 415–17

Keywords: airway, complications; aspiration, equipment; airway

Accepted for publication: November 27, 2007

i-gel (Intersurgical, Wokingham, UK) is a single use supraglottic airway with an anatomically designed mask made of a gel-like thermoplastic elastomer. It has features designed to facilitate insertion, minimize tissue compression, and maintain stability of position after placement. It also has features designed to separate the gastro-intestinal and respiratory tracts; an airway channel connected to a 15 mm port for ventilation and a gastric channel enabling access to and from the upper gastro-intestinal tract and through which a gastric tube may be passed[1] (Fig. 1).

We have been evaluating the i-gel for some time in our hospital and several research projects are underway. After ~280 uses, we have encountered two cases of regurgitation without aspiration and one case of regurgitation with aspiration.

Regurgitation

In two elective cases, clinically evident regurgitation of liquid gastric contents occurred. One patient had no identifiable risk factors for regurgitation and one patient reported mild, infrequent reflux symptoms but had no other risk factors. In both patients (one at the beginning and one at the end of anaesthesia) with spontaneous ventilation, moderate volumes of gastric contents were seen to flow from the drain port of the i-gel. There was no evidence of aspiration clinically or on fibreoptic inspection of the interior of the i-gel and of the laryngeal inlet. Both patients recovered from anaesthesia without complications.

Aspiration

Aspiration occurred during the use of the i-gel in a study to determine ease of use when used by non-anaesthetists. An 85 kg male patient was starved for 16 h before being anaesthetized for elective trapeziectomy. He had previously been given several uneventful general anaesthetics, had no history of gastro-oesophageal reflux, and was a non-smoker, who consumes alcohol occasionally. He was consented and recruited to take part in the study. A medical student was also consented and recruited to the study to insert the device. This student had inserted several LMA-classics® in anaesthetized patients and had undergone manikin training in the use of the i-gel.

The patient was anaesthetized with fentanyl 150 μg and propofol 250 mg. A large dose of propofol was chosen to ensure optimum conditions for placing a supraglottic airway by a novice user. After confirming adequate depth of anaesthesia (unresponsiveness, loose jaw, and lack of response to jaw thrust),[2] the medical student inserted a size 4 i-gel, with jaw thrust applied to aid placement. Gentle manual ventilation was commenced and rapidly followed by coughing and regurgitation of copious amounts of green fluid. The fluid was expelled first from the drain tube and then became visible in the airway tube.

†*Declaration of interest*. Intersurgical has provided i-gels to our department free of charge for evaluation. Dr Cook has received free equipment for evaluation and has been paid by Intavent-Orthofix and the LMA company (competitors of Intersurgical) for lecturing.

Fig 1 The i-gel, sizes 3, 4, and 5.

The patient was turned to the left lateral position, the i-gel removed and his airway suctioned. He continued to regurgitate and was therefore intubated after administration of suxamethonium 100 mg. Fine bore suction down the tracheal tube produced 5–10 ml of green fluid. A nasogastric tube was passed and 40 ml of fluid was removed from his stomach. Anaesthesia and surgery proceeded uneventfully with no hypoxia or signs of significant aspiration. After surgery, the patient was extubated in the left lateral position after further suction of his oropharynx and the nasogastric tube. He made an uncomplicated recovery and was discharged home 4 h later with advice to seek medical advice if any symptoms developed (cough, temperature, or shortness of breath).[3] He made an uneventful recovery.

Discussion

We report three cases of regurgitation during the use of the i-gel in low-risk patients. In two patients, the i-gel enabled early diagnosis of regurgitation and fully protected the airway from aspiration. In the third patient, where the volume and speed of regurgitation was greater, there was minor aspiration, though the bulk of the regurgitant fluid exited from the i-gel drain tube.

The incidence of regurgitation and aspiration with the LMA-Classic® is contentious. It has previously been reported as 1 in 5000 patients,[4] although most would accept that it occurs more frequently than this. Work before the introduction of the LMA-Classic® suggested a risk of aspiration of between 1 in 1100 and 1 in 4000 in starved elective patients.[4 5]

We have used the i-gel ~280 times in this hospital spread unevenly around ~10 regular users. Twenty-six of these were inserted by non-anaesthetists as part of the trial to examine the insertion of the i-gel by non-anaesthetic staff. A report of this study is in preparation. The i-gel has only been used in starved patients at low risk of aspiration, the vast majority of who were undergoing elective minor surgery. Although we have now observed three patients of regurgitation, we do not think that this offers evidence of an increased risk of regurgitation with this device. It is likely that if a standard laryngeal mask had been used for these patients the regurgitation would not have been apparent: none of the patients presented with symptoms suggestive of aspiration except minor coughing in one patient. It was the presence of gastric contents exiting the drain tube that alerted the anaesthetist to its occurrence. The incidence of *asymptomatic* regurgitation to the upper oesophagus (and indeed aspiration) with a standard laryngeal mask is not known; however, in one study, in paralysed patients, reflux occurred in 5 of 10 patients during maintenance and in 8 during reversal/emergence.[6] None of these patients showed any clinical signs of reflux.

Another reason for the apparently high incidence of regurgitation might be the use of an unfamiliar device. This could certainly be postulated as a reason for the case of aspiration with a novice user. However, the other cases occurred with experienced users and not all occurred at the beginning of anaesthesia (as would be expected if poor technique had caused excessive pharyngeal stimulation).

Is it possible to estimate the incidence of regurgitation or aspiration with the i-gel? Because of the difficulty in diagnosing regurgitation and aspiration and uncertainties about the reporting of events, we suggest that such estimates are speculative. At one extreme, if we include only the patients in our hospital, we might conclude an incidence of regurgitation of 3/280 (1.1%) and of aspiration of 1/280 (0.36%). At the other extreme, if we consider that other cases of regurgitation and aspiration with a new device are likely to have been reported, we should include more than 200 000 i-gel using cases worldwide in our calculations (David Chapman, Intersurgical, personal communication). If we consider only clinically significant aspiration (ours was not), the incidence of regurgitation is <3 in 200 000 ($<0.0015\%$; upper limit of 95% confidence interval, 0.0045%) and of aspiration, 0 in 200 000 (0%, 95% confidence limits 0–0.0015%) patients. The best that can be said is that the incidences of regurgitation and aspiration associated with the i-gel airway are low and that, so far as we are aware, to date there have been no reports of patients coming to harm as a result of aspiration and regurgitation associated with the use of the the i-gel airway.

There are now several supraglottic airways marketed that are specifically designed to reduce the risk of aspiration. Five devices are designed to separate the respiratory and gastro-intestinal tracts: the i-gel, laryngeal tube

suction mark II (LTS II) and its disposable version (LTS-D) (VBM GmbH, Sulz, Germany), the proseal laryngeal mask airway (PLMA), the recently introduced laryngeal mask airway Supreme® (Intavent Orthofix, Maidenhead, UK), and the streamlined liner of the pharynx airway (SLIPA). The device SLIPA (Teleflex Medical, High Wycombe, UK) is designed to prevent aspiration through its large internal capacity acting as a reservoir into which regurgitant fluid can accumulate rather than entering the larynx. These devices might be considered as a new generation of supraglottic devices compared with predecessors such as the standard laryngeal masks that do not incorporate such features. They offer the opportunity (and the temptation) to expand the indications for the use of supraglottic airways and in particular to increase their use during controlled ventilation, in the obese and as a rescue device during cardiopulmonary resuscitation. However, for most of these devices, the efficacy of these design features, either in separating the gastro-intestinal and respiratory tracts or in preventing aspiration, has not been tested and is simply assumed. The device for which there is most evidence is the PLMA.[7 8]

Two studies examined the degree of protection of the airway provided by the PLMA during simulated regurgitation. In a bench-top study using a model designed around the SLIPA, fluid was injected into the model oesophagus at variable rates and the onset and extent of entry of fluid into the model trachea was examined.[7] This study showed considerable protection from aspiration by the PLMA (and SLIPA) in comparison with the LMA-Classic®. When high-injection rates were used, the volume of fluid entering the model trachea increased, presumably as the protective designs were overwhelmed. It is not clear how relevant this bench model is to reality. A more important study was performed in fresh cadavers whose airway was either left open or maintained with a LMA-Classic® or PLMA inflated to lesser or greater degrees.[8] The oesophagus was incrementally filled with fluid and pressurized. The oropharynx and larynx were continually observed for evidence of fluid. Notably, the LMA-Classic® provided a considerable degree of airway protection. The PLMA provided complete airway protection when the drain tube was patent and enhanced protection even with the drain tube clamped. This and other research offer robust evidence of the airway protective effects of the PLMA. No such data are available for the i-gel.

When comparing the PLMA with the i-gel, there are several differences which might lead to performance differences. The i-gel has no inflatable cuff and its airway seal is likely to be somewhat lower than that of the PLMA (though higher than that of the LMA-Classic®).[9] In addition, the drain tube of the i-gel (French 12 gauge for sizes 3 and 4 and French 14 gauge for size 5) is smaller than for the PLMA (French 16 gauge in a size 4 PLMA). It is also perhaps more deformable at its distal end than is the PLMA. The effects of these differences cannot be determined without formal study, but it is certainly plausible that the smaller, deformable drain tube of the i-gel may not manage regurgitant fluid as well as the PLMA.

If these newer devices offer protection against aspiration, might they have an enhanced role in the management of the difficult airway? The i-gel does not appear in any advanced/difficult airway algorithms to date and it would be inappropriate for it to be included before considerably more clinical data on efficacy and safety are available. However, it has many features that may make it suitable for airway rescue, airway protection, and use by novices:[9 10] this would be a useful area for further research.

This case series indicates that the drain tube of the i-gel allows early identification of regurgitation and allows some egress of gastric contents when it occurs. This in itself offers benefit. It does not tell us whether regurgitation is less or more likely with the i-gel than the LMA-Classic®, or PLMA, and neither does it tell us whether the i-gel provides improved airway protection compared with the LMA-Classic®, or PLMA. These are important clinical questions, and research that addresses these questions is required before the i-gel can be recommended for the advanced uses that the PLMA is.

References

1 Intersurgical*i-Gel User Guide*. Berks: Wokingham.
2 Drage MP, Nunez J, Vaughan RS, Asai T. Jaw thrusting as a clinical test to assess the adequate depth of anaesthesia for insertion of the laryngeal mask. *Anaesthesia* 1996; **51**: 1167–70
3 Warner MA, Warner ME, Weber JG. Clinical significance of pulmonary aspiration during the peri-operative period. *Anesthesiology* 1993; **78**: 56–62
4 Brimacombe JR, Berry A. The incidence of aspiration associated with the laryngeal mask airway: a meta-analysis of the published literature. *J Clin Anesth* 1995; **7**: 297–305
5 Olsson GL, Hallen B, Hambraeus-Jonzon K. Aspiration during anaesthesia: a computer aided study of 185 358 anaesthetics. *Acta Anaesth Scand* 1986; **30**: 84–92
6 Valentine J, Stakes AF, Bellamy MC. Reflux during positive pressure ventilation through the laryngeal mask. *Br J Anaesth* 1994; **73**: 543–4
7 Miller DM, Light D. Laboratory and clinical comparison of the Streamlined Liner of the Pharynx Airway (SLIPA™) with the laryngeal mask airway. *Anaesthesia* 2003; **58**: 136–42
8 Keller C, Brimacombe J, Kleinsasser A, Loekinger A. Does the ProSeal laryngeal mask airway prevent aspiration of regurgitated fluid? *Anesth Analg* 2000; **91**: 1017–20
9 Gabbott D, Berenger R. The iGEL supraglottic airway: a potential role for resuscitation? *Resuscitation* 2007; **73**: 161–2
10 Sharma S, Rogers R, Popat M. The i-gel™ airway for ventilation and airway rescue. *Anaesthesia* 2007; **62**: 419–20