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Original Article

An observational study of the Baska® mask: a novel supraglottic airway*

V. Alexiev,[1] A. Salim,[2] L. G. Kevin[3] and J. G. Laffey[4]

1 Clinical Tutor, 2 Specialist Registrar, 3 Consultant and Senior Clinical Lecturer, 4 Professor, Department of Anaesthesia and Intensive Care Medicine, Galway University Hospitals; Anaesthesia, School of Medicine, Clinical Sciences Institute, National University of Ireland, Galway; and Galway HRB Clinical Research Facility, National University of Ireland, Galway, Ireland

Summary

The Baska mask is a novel supraglottic airway device. We conducted an initial observational study to assess this device in 30 low-risk female patients. All Baska masks were inserted by a single investigator. The overall success rate for device insertion was 96.7% (95% CI 82.8–99.9%), while the success rate for the first insertion attempt was 76.7% (95% CI 57.7–90.1%). The device was easy to insert, with a mean (SD) difficulty score of 0.9 (1.6) on a 10-cm scale. The mean (SD) airway leak pressure was 35.7 (13.3) cmH_2O. The incidence of throat pain, dysphonia and dysphagia was low. We conclude that the Baska mask demonstrates a level of utility as an alternative supraglottic airway that is worthy of further clinical study.

Correspondence to: J. Laffey
Email: john.laffey@nuigalway.i.e
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Supraglottic airways are increasingly used for airway management in patients undergoing general anaesthesia [1, 2]. The Baska mask (Logikal Health Products PTY Ltd., Morisset, NSW, Australia) is a novel supraglottic airway device. It has many of the features of other supraglottic airways, with a number of innovations (Fig. 1). These include a non-inflatable cuff, which is moulded to take up the shape of the supraglottic airway, potentially reducing the risk of oropharyngeal tissue and/or nerve damage induced by cuff overinflation, a known complication with other supraglottic airways [3]. However, the cuff differs from other 'non-inflatable' cuffs in that it is continuous with the central channel of the device (Fig. 1 (b)). As the pressure increases with positive pressure ventilation, the cuff itself is 'inflated', which may improve the seal, reducing leak and make ventilation more efficient. The Baska mask incorporates an inlet that fits into the upper oesophagus, and the dorsal surface of the cuff is moulded to direct any oropharyngeal contents away from the glottis and towards the side channels to which suction can be attached to facilitate aspiration of this space (Fig. 1 (c)). These features may reduce the risk of pulmonary aspiration of secretions or gastric contents that accumulate in the supraglottic area. In addition, there is integrated bite-block, which reduces the risk of patients' biting and blocking the airway. There is an extended hand-tab attached to the cuff that permits the operator to control the degree of flexion of the device during the insertion. The Baska mask comes in 4 sizes, ranging

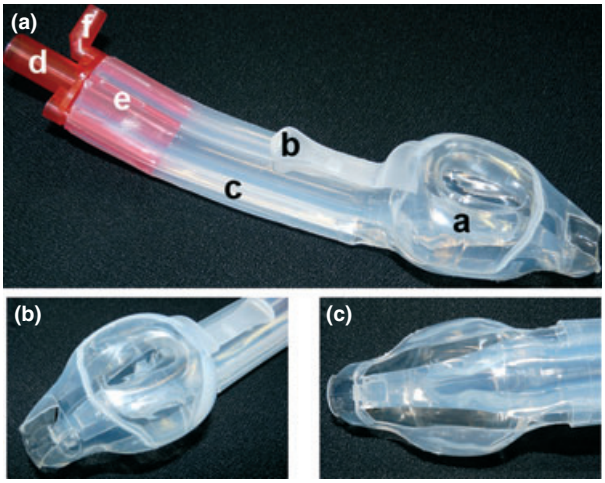

Figure 1 The Baska mask. Panel (a): a – cuff; b – tab used to flex the cuff during placement; c – side suction channels; d – central airway channel; e – bite block; f – suction connector. Panel (b): close-up of the anterior (glottic) surface of the non-inflatable cuff. Panel (c): dorsal surface of the cuff, with the pharyngeal drainage sump reservoir, which drains into the bilateral suction channels.

from paediatric to adult [4]. Lastly, the Baska mask is inserted in the neutral head position, which may reduce the need for neck manipulation.

To our knowledge, there are no studies published on the Baska mask to date. We wished to perform an initial evaluation of the Baska mask in terms of success rate, ease and speed of insertion, performance during general anaesthesia and rate of complications in low-risk patients requiring anaesthesia for minor surgical procedures.

Methods

After obtaining approval from the Galway University Hospitals Research Ethics Committee (Galway, Ireland), and written informed patient consent, we studied 30 female patients of ASA physical status 1–3 and aged 18 years or older, who were deemed on pre-operative assessment by their primary anaesthetist to be at low risk for difficult tracheal intubation. Other inclusion criteria included a body mass index (BMI) of 20–35 $kg.m^{-2}$ and non-urgent surgery of planned duration 0–2 h. Exclusion criteria included patients' refusal or inability to give informed consent, neck pathology, previous or anticipated problems with the upper airway or the upper gastrointestinal tract, live pregnancy and increased risk of gastric aspiration.

All patients received a standardised general anaesthetic [5, 6]. Standard monitoring, including ECG, non-invasive blood pressure, pulse oximetry and end-tidal gas monitoring, was utilised throughout. Before induction of anaesthesia, patients were given fentanyl (1–1.5 $\mu.kg^{-1}$) intravenously. The dose of propofol (2.5–4.0 $mg.kg^{-1}$) was titrated to induce anaesthesia following which the lungs were manually ventilated with sevoflurane (2.0–4.5%) in oxygen.

One investigator (VA) with > 10 years' experience (but < 10 prior insertions with the Baska mask) performed all device insertions according to the manufactures' instructions [4]. A maximum of three attempts at Baska mask placement was permitted per patient. The size of Baska mask used for the first attempt was based on the patient's weight as per the manufacturer's instructions. If the device did not function effectively, the following manipulations were performed in sequence: the depth of insertion was increased; the device was rotated, and the device was withdrawn slightly. If these manoeuvres were unsuccessful in achieving an effective airway, the device was removed. If the problem was predominantly due to a large leak, a device one size larger was re-inserted. If the device size was deemed large, a smaller sized Baska mask was inserted. If insertion failed after three attempts, a laryngeal mask airway (LMA) was inserted. If this failed, tracheal intubation was performed. Thereafter, in all patients, the lungs were mechanically ventilated until spontaneous ventilation supervened. Anaesthesia was maintained with sevoflurane (2.0–4.5%) in a mixture of air and oxygen. Further management was left to the discretion of the anaesthetist providing care for the patient.

All data were collected by an unblinded observer. The duration of a device insertion attempt was defined as the time from the moment the device was taken up by the operator until successful ventilation was achieved or the device was removed [7, 8]. Successful ventilation was defined as the presence of bilateral chest expansion, a satisfactory end-tidal carbon dioxide tracing with plateau and 'an estimated leak' of less than 30% of the inspired tidal volume [9, 10]. We recorded the number

and duration of insertion attempts, manipulations and ease of insertion as rated by the operator on a 10-cm visual analogue scale (VAS), and the presence of leak 0 and 5 min after insertion.

A 'leak test' was performed as previously described [11, 12]. Briefly, while the patient was apnoeic, and following confirmation of adequate ventilation, the adjustible pressure limiting valve was closed to 70 cmH_2O, the fresh gas flow was set at 6 $l.min^{-1}$, and the airway pressure was measured on the breathing circuit pressure gauge. 'Leak pressure' was defined as the plateau airway pressure that was achieved. In patients in whom the airway pressure reached 50 cmH_2O, the leak test was interrupted and a value of 50 cmH_2O was recorded. The stability of the placement of the Baska mask was then assessed by determining the leak fraction while the patient received volume controlled ventilation in four different head positions: neutral; rotated to right; head extended; and pillow removed. Leak fraction was calculated according to the formula: [Vinsp − Vexp] / Vinsp × 100. We monitored patients for the following complications: arterial oxygen desaturation; lip damage; blood staining on mask removal; and laryngospasm [7, 8]. We evaluated the incidence and severity of throat pain, dysphonia and dysphagia at arrival and discharge from the post-anaesthesia care unit and on the next postoperative day using a 10-point verbal rating scale (VRS).

We planned to enrol a minimum of 20 and a maximum of 50 patients in this study (Fig. 2). A priori, we stipulated that once the 20th patient was recruited, an independent observer would examine the data to determine whether following criteria were fulfilled: (1) five consecutive successful Baska mask insertions on the first attempt; (2) five consecutive mask insertions each less than 30 s in duration; and (3) five consecutive mask insertions with mean leak < 10%. When these criteria were all fulfilled, the study would be terminated. If all three criteria were not fulfilled, five additional patients would be recruited and the data re-examined at that point. Recruitment would continue until the criteria were fulfilled or until 50 patients were recruited, at which stage the study would be terminated.

Results

The study was stopped after the recruitment of 30 patients as the stopping criteria were fulfilled. The

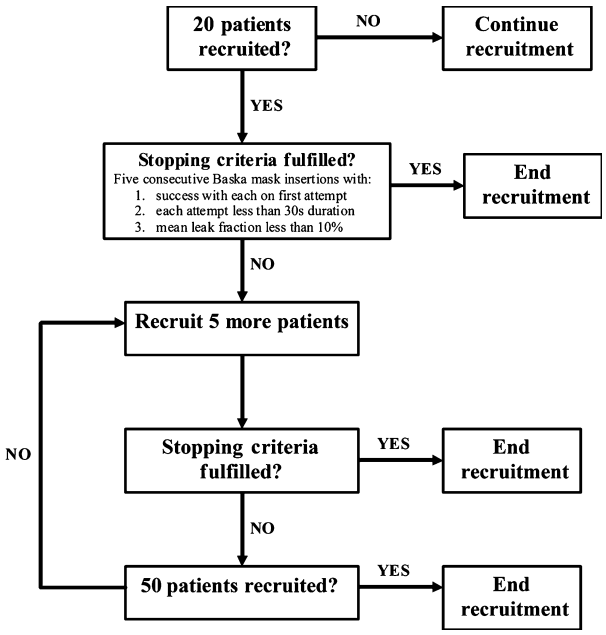

Figure 2 Flowchart depicting patient recruitment algorithm.

characteristics of the patients enrolled in the study are given in Table 1. The majority were undergoing ambulatory gynaecological surgery, with the remainder undergoing breast surgery or other minor procedures.

The data for insertion of the Baska mask are given in Table 2. In 23 of 30 patients (76.7%), the Baska mask was successfully inserted on the first attempt. Four patients required two insertion attempts, while three required three insertion attempts. The overall success rate for the Baska mask was 96.7%, with only one patient requiring an alternative airway device (a LMA). However, the upper limit of the 95% CI (calculated using the binomial distribution [13]) for overall device insertion failure rate was 17.2%, while the upper limit of the 95% CI for first attempt insertion was 42.3%. The mean duration of the successful insertion attempt of the Baska mask was 23.9 (13.3) s, while the mean (SD) duration of the first insertion attempt was 32.2 (29.8) s. Importantly, the duration required to insert the mask progressively decreased over time as the investigator became more adept with the device, with a mean time of just over 10 s required for the last five patients (Fig. 3). In 25 of the 30 patients, a Baska size-4 mask was used, with a size-5 mask used in the remaining four patients.

There was an audible leak from the mask during positive pressure ventilation at insertion of the mask in

Table 1 Characteristics of 30 patients enrolled into the study. Values are mean (SD), median [IQR (range) or number (proportion).

Age; years	47.5 (13.3)
Body mass index; $kg.m^{-2}$	27.6 (4.6)
ASA physical status	2 (1–2 [1–3])
Airway measurements	
Thyromental distance; cm	7.6 (2.0)
Inter-incisor distance; cm	5.5 (1.2)
Mallampati classification	1 (1–2 [1–2])
1	17 (57%)
2	13 (43%)
3	0
4	0
Type of surgery	
Hysteroscopy/dilatation & curettage/ERPC	13 (43%)
Laparoscopy	8 (27%)
Cystoscopy	2 (7%)
Others	7 (23%)
Induction of anaesthesia	
Fentanyl dose; $\mu.kg^{-1}$	1.4 (0.3)
Propofol dose; $\mu.kg^{-1}$	3.2 (0.7)
End-tidal sevoflurane at device insertion; %	4.8 (1.1)
Duration; min	
Anaesthesia	27.2 (15.9)
Surgery	22.7 (15.7)
Time to resumption of spontaneous ventilation	21.8 (14.3)

Table 2 Data regarding insertion of Baska mask and complications in 30 patients. Values are number (proportion), median [IQR (range) or mean (SD).

Overall success rate	29 (97%)
Number of insertion attempts	1 (1–1 [1–3])
1	23 (77%)
2	4 (13%)
3	3 (10%)
Size of Baska mask inserted successfully	
4	25 (83%)
5	4 (13%)
6	0 (0)
Measured mask leak; %	
Supine	5 (3–15 [1–43])
Head rotated	8 (5–15 [2–55])
No pillow	10 (5–17 [1–36])
Head extended	8 (5–16 [1–43])
Arterial oxygen saturation during attempt	
Lowest saturation; %	98 (3)
Patients with saturation SaO_2 < 90%	1 (3%)
Patients with saturation < 85%	0
Severity of throat discomfort	
On arrival in PACU	0 (0–0 [0–6])
On discharge from PACU	0 (0–0 [0–2])
1st postoperative day	0 (0–0 [0–6])
Severity of dysphonia	
On arrival in PACU	0 (0–0 [0–6])
On discharge from PACU	0 (0–0 [0–6])
1st postoperative day	0 (0–0 [0–6])
Severity of dysphagia	
On arrival in PACU	0 (0–0 [0–2])
On discharge from PACU	0 (0–0 [0–1])
1st postoperative day	0 (0–0 [0–0])

PACU, post-anaesthesia care unit (interquartile range [range]).

nine of the 30 patients, seven of whom were in the first 10 patients recruited. Of these nine patients, only three had a persistent audible leak 5 min after insertion, suggesting that the cuff seal improved over time. The mean (SD) leak pressure was 35.7 (13.3) cmH_2O. Of interest, the leak pressure was initially relatively low, being < 20 cmH_2O for the first five patients, suggesting a sub optimal seal at the glottis aperture. However, the leak pressure progressively increased with subsequent patients, again suggesting a learning effect (Fig. 4). In the final 20 patients of the cohort, the mean leak pressure was > 40 cmH_2O. Of note, in two patients, the leak test was terminated prematurely due to the development of a reflex bradycardia. The pressure at the time of termination of the measurement was taken as the leak pressure, which is a likely underestimate of the true leak pressure. We evaluated the stability of the mask position by determining the leak fraction in different head. Leak fraction increased slightly from a median of 5.4% in the supine position to a maximum of 9.8% following removal of the pillow. However, this change is unlikely to be of clinical importance.

The device was found to be relatively easy to insert, with a mean (SD) VAS insertion difficulty score of 0.9 (1.6) out of 10. Again, there was a learning effect, with initial VAS device difficulty scores for the first five patients being substantially higher than the scores for later patients (Fig. 5). The incidence of throat pain, dysphonia and dysphagia was low (Table 2). There was no episode of arterial desaturation below 85% and just one patient had a transient arterial desaturation below 90% (Table 2). In this case, the saturations dropped to 87% and were corrected within 1 min. The episode was probably related to a prolonged attempt at optimising the mask position in an obese (BMI 33 $kg.m^{-2}$) patient. Mean arterial saturations were high, and did not alter

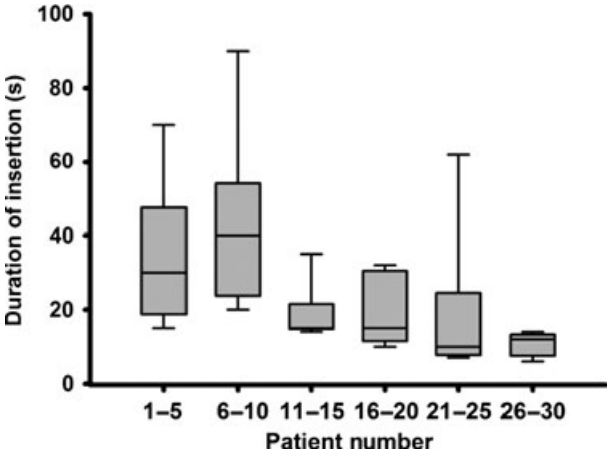

Figure 3 Box-whisker plot demonstrating the decrease in the mean duration of insertion for successful attempts at Baska mask placement with each subsequent group of five patients. Horizontal line, median; box, IQR; whiskers, range.

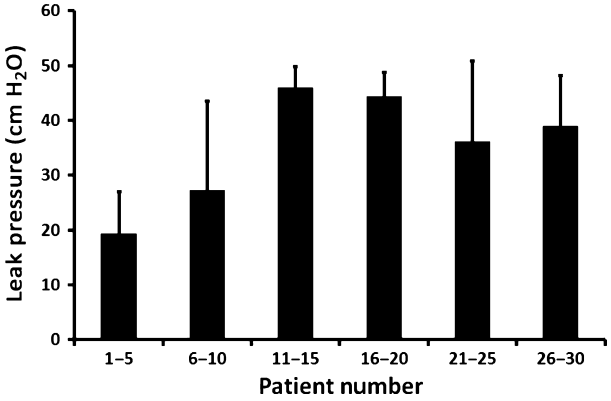

Figure 4 Histogram demonstrating the increase in mean leak pressures with the Baska mask with each subsequent group of five patients. Error bars indicate SD.

with increasing experience with the Baska mask. The only complication was minor bleeding (blood staining of mask in seven patients), and there were no instances of laryngospasm or lip injury. The severity of throat discomfort, dysphagia and of dysphonia was low (Table 2).

Discussion

These data represent the first published findings, to our knowledge, regarding the Baska mask. Overall, we found that the device functioned reasonably well in this initial

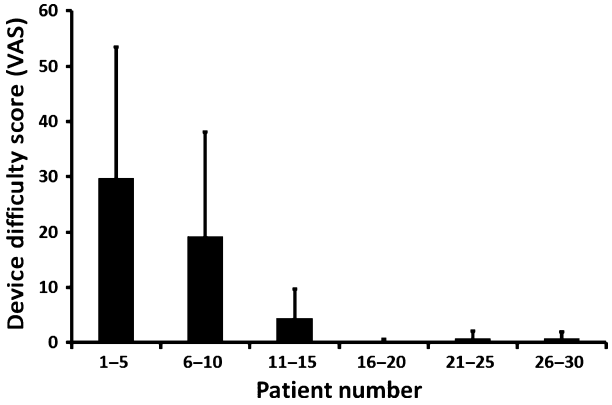

Figure 5 Histogram demonstrating the decrease in device difficulty scores with the Baska mask with each subsequent group of five patients. Error bars indicate SD.

study. As might be expected from an inexperienced user, successful placement on first insertion attempt, device insertion times, leak pressures and user-rated difficulty all progressively improved over time as additional experience and learning were accumulated. The leak pressures achieved with the Baska mask compared well with data from other supraglottic airways such as the LMA, i-gel and ProSeal [9–12]. Our data suggest that, after the first 10 patients, there was a sustained improvement in each of these outcome measures, with duration of placement attempts below 20 s, and leak pressures consistently over 30 cmH_2O. This provides reassurance that the learning curve for this device may be relatively short, although additional studies are required to explore the learning curve in more detail [14, 15]. The relatively low complication rate and absence of serious complications are also encouraging.

We did encounter some difficulties with the Baska mask, particularly in earlier insertion attempts. First, we found that very precise positioning of the cuff orifice against the glottis is necessary to ensure adequate ventilation. When correctly positioned, the seal is good, but repeated adjustment of the depth of insertion of the mask may be required to minimise leaks. Initially, we did not insert the mask to a sufficient depth, and then found we had to advance the device further, against some resistance, to get a good seal. Secondly, we found that the leak around the mask progressively decreased over time with positive pressure ventilation. This is presumably due to improvement of the cuff seal with the

glottis aperture with each positive pressure inflation. Thirdly, the removable connector piece for the suction port was occasionally loose, creating a risk that it could detach and fall into the airway. However, we understand from the manufacturers that this connector is not detachable in newer versions.

This study is an observational study and has limitations. Our trial does not, for example, meet the minimum requirements of a 'Level 3b' clinical trial that the Difficult Airway Society now recommends that novel airway management undergo, before anaesthetists use or purchase the device [16, 17]. Despite our carefully planned sequential recruitment strategy, the final sample size was quite small and this mandates caution when considering the implications of the relatively low incidence of overall failure of device insertion. This is well illustrated by the fact that the upper limit of the 95% CI for failure rate was high [13]. However, our study was not designed to provide evidence to justify the use of this novel device. Rather it was an initial observational study conducted in the smallest number of patients in which we felt we could derive some useful information regarding the device. The study was restricted to adult females to reduce variability, particularly with regard to the size of the Baska mask required. Initial studies in male patients suggested greater variability with regard to the sizing of the Baska mask. The study was not blinded and therefore patient as well as investigator bias was possible. Both the ease of insertion VAS score and the patient discomfort VRS are subjective measures and open to bias. All devices were sited by one experienced anaesthetist. The investigator had limited exposure to this device before the study (< 10 placements).

We conclude that the Baska mask demonstrates a level of utility as an alternative supraglottic airway that is worthy of further clinical study.

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Competing interests

No other funding or competing interests declared.

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