Evaluation of the Efficacy of the Baska Mask

by

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Declaration

The author declares that this thesis is his own work and that no degree was obtained in the National University of Ireland, Galway, or elsewhere, on the basis of this work.

The Baska™ masks and Ambu® Scopes™ used in the trials described in this work were provided free of charge by Pro-Act Medical, UK. Neither the inventor nor the supplier of these devices had contributed input to the design, execution or interpretation of the findings of these trials. All other resources came from departmental funds.

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Dedication

I would like to dedicate this thesis to my parents Lubica and Slavi, and to all my teachers, who showed me so many wonderful things.

Abbreviations

ASA	American Society of Anesthesiologists
BMI	Body Mass Index
BP	Blood Pressure
bpm	Beats per minute
CC	Creative Commons (License)
CI	Confidence Interval
cLMA	Classic Laryngeal Mask Airway
cm	Centimetre
COPA	Cuffed Oropharyngeal Airway
DAS	Difficult Airway Society
D&C	Dilatation and Curretage
ECG	Electrocardiogram
ENT	Ear Nose Throat
ERPC	Evacuation of Retained Products of Conception
$EtCO_2$	End-tidal CO_2
ETT	Endotracheal Tube
GI	Gastrointestinal
ICU	Intensive Care Unit
IQR	Inter-Quartile Range
kg	Kilogramme
LMA	Laryngeal Mask Airway
MAP	Mean Arterial Pressure

mg	Milligramme
mm	Millimetre
PACU	Post-Anaesthesia Care Unit
PEEP	Positive End-Expiratory Pressure
POGO	Percentage of Glottic Opening
p-value	Probabilty Value
µg	Microgramme
RCT	Randomised Controlled Trial
s	Second
SAD	Supraglottic Airway Device
SD	Standard Deviation
SLIPA	Streamlined Liner of the Pharynx Airway
SpO_2	Peripheral Oxygen Saturation
VAS	Visual Analogue Scale
V_{exp}	Expired Volume
V_{insp}	Inspired Volume
VRS	Verbal Rating Scale

1. Introduction

1.1. Airway Management and Anaesthesia - a brief historical note

There is historical evidence of attempts at airway management thousands of years ago. Images of tracheotomy were found on Egyptian tablets that are over 5000 years old and the procedure is referred to in a 4000 year old Hindu text [1]. In the 2nd century Claudius Galenius studied the airway anatomy on animals and suggested that the lungs could be inflated via a tube passed through the larynx [2]. In the 16th century Andreas Vesalius performed autopsies and described in detail the human anatomy [3]. Subsequently, Aristotle's concept of relationship between structure and function [4] could be put to work and rapid advancements in the knowledge of physiology ensued. Vesalius, William Harvey, Claude Bernard, Ivan Pavlov and many others built the foundations of modern physiology. The advancements in understanding of the functioning of the human body permitted the development of strategies to supplement and modify some physiologic processes. In the 18th century William Tossach and John Fothergill described and promoted the concept of mouth-to-mouth ventilation [5].

Humans have used herbal extracts and alcohol to alleviate pain and to make surgical procedures tolerable for thousands of years. Sumerians cultivated the opium poppy [6], while Incas used coca leaves for local anaesthesia [7]. In the 16th century Paracelsus examined the analgesic effects of ether on animals [8]. In the 18th century Joseph Priestley, Thomas Beddoes, James Watt and Humphry Davy studied the effects of nitrous oxide [9-11]. In the 19th century the knowledge of anaesthetic gases, human anatomy and physiology, physics, chemistry and engineering reached levels that allowed for the birth of general anaesthesia. In the early 1840s ether was being used on both sides of the Atlantic [12, 13]. William Morton's public demonstration of ether anaesthesia in Massachusetts General Hospital in 1846 was received well by the professional community [14]. The practice of anaesthesia rapidly gained popularity. The potential for loss of airway protection associated with anaesthesia created a need for effective approaches to airway management.

This promoted advancements in airway management equipment and techniques.

Eugene Bouchut, Wilhelm Hack and William Macewen independently reported the use of orotracheal intubation in the second half of the 19th century [15-17]. Of note, the concept of tracheal intubation and ventilation had been described much earlier by Avicena and Andreas Vesalius in *Canon of Medicine* and *De humani corporis fabrica*, respectively, as described by Baker in his historical overview which consulted these works [18]. In the 1930s, a few supraglottic airway devices (SADs) were developed, amongst them the Guedel airway [19] and the Pharyngeal bulb gasway [20]. In 1965 McDonald and Stocks reported intubation in neonatal patients [21]. In 1981 Archie Brain used the prototype Laryngeal mask airway (LMA) for the first time [22]. The first commercially available version – the LMA Classic™ - enjoyed rapid uptake. Improved versions followed, amongst them the LMA Flexible™ (1990), the LMA Fastrach™ (1997), the LMA Unique™ (1997), the LMA ProSeal™ (2000), the LMA CTrach™ (2005) and the LMA Supreme™ (2007). Alternative devices were also developed – e.g. i-gel®, SLIPA™, COPA™, Combitube® [23]. Kanag and Meenakshi Baska released the Baska™ mask in 2011.

1.2. The Human Airway - a brief anatomical note

The human airway (Figure 1.1) is divided into upper (the nasal, oral and pharyngeal pathways, and the larynx) and lower respiratory tract (the trachea and the bronchial tree). The transition between them occurs at the larynx.

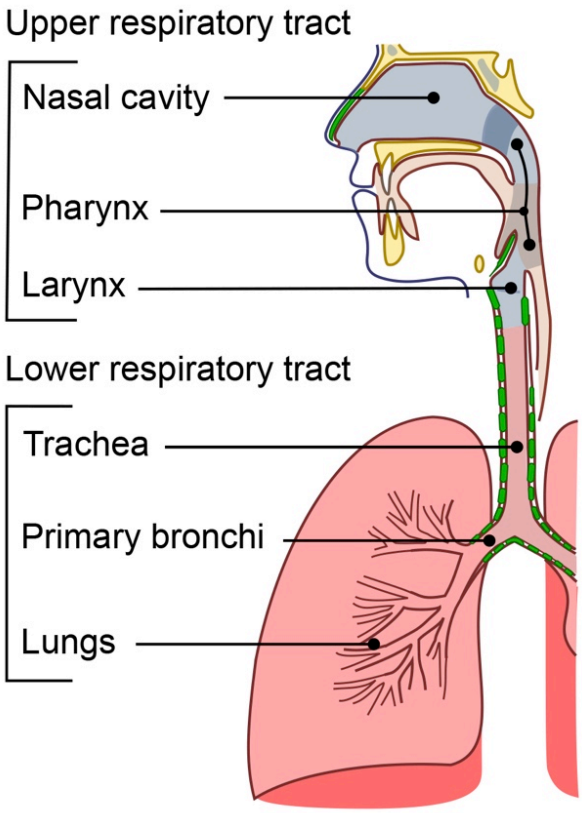

Figure 1.1. The human airway.

Original picture "Conducting passages of the human respiratory system" by Lord Akryl, downloaded from Wikipedia.org as "No Copyright" file under CC.

The larynx (Figure 1.2) provides an entrance to the lower respiratory tract and separates it from the gastrointestinal tract. Almost all airway devices either lie in its proximity or pass via it.

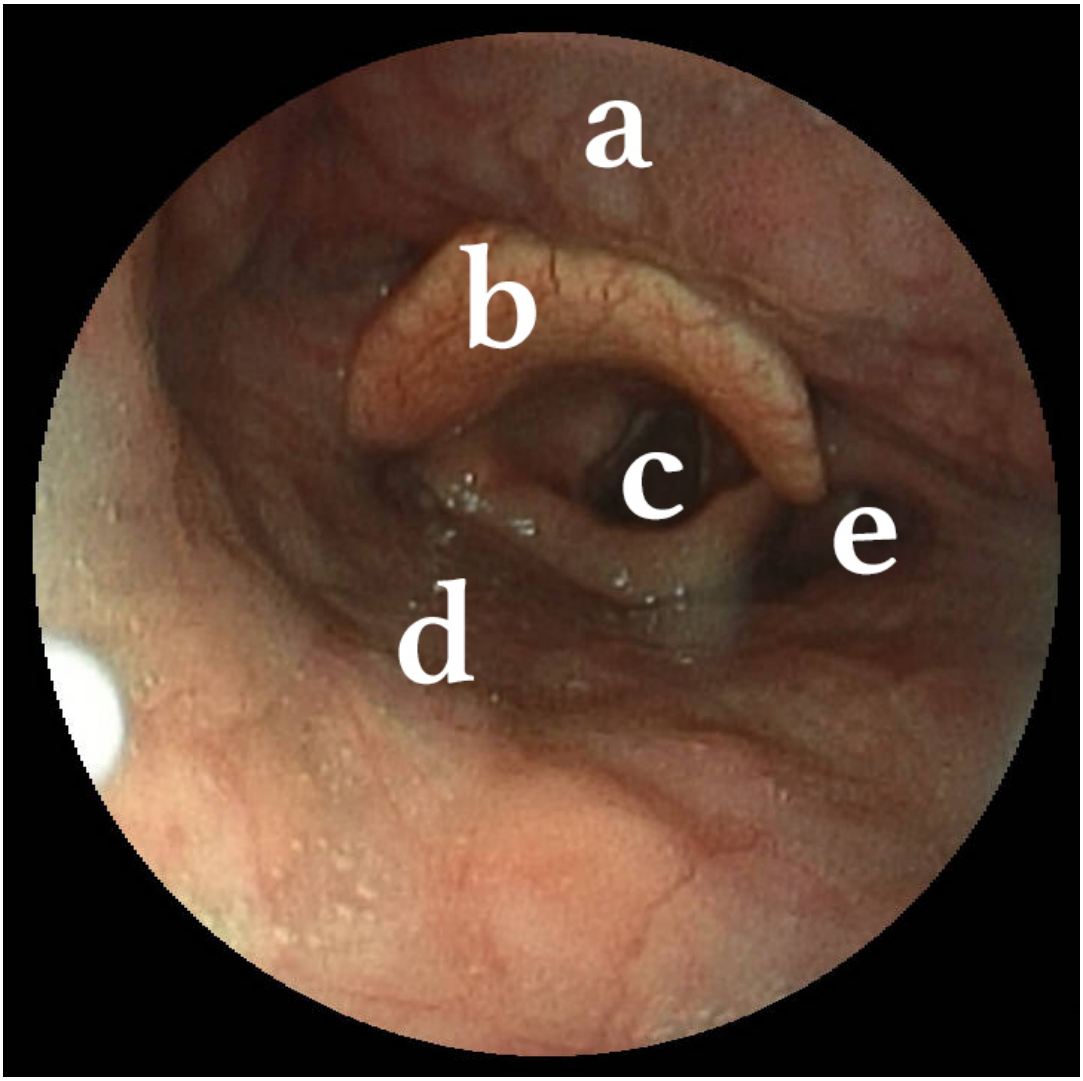

Figure 1.2. The larynx and the peri-laryngeal structures.

This fibreoptic view from the nasopharynx illustrates the tongue base (a), the epiglottis (b), the laryngeal inlet (c), the posterior pharyngeal wall (d) and the pyriform fossae (e).

Modified image. Original picture “Normal Epiglottis” by Med Chaos, downloaded from Wikipedia.org under CC BY-SA 3.0 license.

The nasal pathways are the dominant conduit between the outside environment and the pharynx in the awake patient, warming and humidifying the inhaled air. In anaesthetised and critically ill patients the oral cavity gains higher importance as the main conduit for insertion of airway management devices [24]. Its size allows for the passage of airway devices or imaging equipment of larger dimensions when compared to the nasal pathways.

The airway devices are used to maintain the patency of the patient's respiratory tract, to effect an airway seal in order to enable positive pressure ventilation, and to protect the lower respiratory tract from aspiration. Based on their position, the airway devices can be broadly divided into external, supraglottic and infraglottic. The face mask (applied over the patient's mouth and nose, see Section 1.3.1) is an external airway device. Examples of supraglottic airway devices (SADs) include the Guedel airway (placed in the oropharynx above the laryngeal inlet, see Section 1.3.3.1) and the laryngeal mask airway (placed in the pharynx and covering the laryngeal inlet, see Section 1.3.3.2). The endotracheal tube (passed via the larynx into the trachea, see Section 1.3.2) is an example of an infraglottic device.

The airway devices differ in many aspects, amongst them invasiveness, ease of device use, quality of airway seal, level of protection from aspiration, and patient comfort indices. For example, the cuffed endotracheal tube offers superior airway seal and protection from aspiration yet it requires additional equipment and significant skill to place it. In contrast, the SADs are easier to insert and result in less patient discomfort yet the quality of the airway seal and the level of protection from aspiration is inferior to that of the cuffed ETT. More in-depth discussion of these differences is offered in Section 1.3.

The airway devices have impact on the neighbouring anatomical structures and vice versa. For example, oral insertion of an endotracheal tube or a SAD may result in lip, soft palate or dental trauma. The cuff of many SADs surrounds the laryngeal inlet and exerts pressure on the tongue base, the epiglottis, the pharyngeal mucosa and the submucosal structures (including nerves). This

may affect the blood flow and result in tongue swelling or nerve injury. On the other side, the epiglottis may obstruct the SAD cuff orifice and result inability to ventilate the patient [25].

The interactions between the airway devices and the surrounding anatomical structures must be taken into consideration when the devices are designed and used [25, 26]. Furthermore, appreciation of the importance of the crossover of the gastrointestinal and airway pathways in the pharynx is critical.

1.3. Airway Management Devices

The “ideal airway device” should be user friendly, have high success rates and a good safety profile in a wide range of clinical scenarios (Table 1.1).

Table 1.1. Airway device desirable properties

Short learning curve
Simple and reliable sizing guidelines
User friendly
Suitable for wide range of clinical situations
High success rate
Fast placement
Good airway seal
Good protection from aspiration
Low incidence of intraoperative displacement / need for repositioning
Low incidence of complications (laryngospasm; damage to lips, teeth, nerves, vocal cords or other structures; sore throat, dysphonia, dysphagia etc.)
No known safety concerns regarding the device material
Low infection transmission risk (single use)
Low cost
Low environment impact

Anaesthetists and other specialties involved in airway management, whether inside the operating room or elsewhere (e.g. pre-hospital, emergency room etc.) currently have multiple airway management devices at their disposal. When deciding which one to use, the practitioner should take into account the operator factors (skill base, availability of backup etc.); the scenario specifics (urgency of the situation, quality of the support team, availability of additional equipment and expertise, etc.); the procedure type (position, duration, complexity, factors related to the surgeon, etc.); the patient characteristics (fasting status, weight, expected airway difficulties etc.); and professional development goals (e.g., teaching a trainee, or maintaining skill in particular technique). The obese patient undergoing extensive spinal surgery in the prone (facedown) position would be a good candidate for placement of a cuffed endotracheal tube (ETT). Managing airway complications in the prone position can be challenging and the ETT (Section 1.3.2) provides excellent airway seal and good airway stability when properly secured. In the slim fasting patient undergoing a minor procedure in the supine position, a supraglottic airway device (or indeed a facemask) would often be the obvious choice, as the SADs (Section 1.3.3) are less invasive as compared to the ETT and the management of potential airway complications is easier in supine position. In some instances there are differing opinions regarding device suitability in the particular settings (e.g., supraglottic airway device use in laparoscopic surgery [27-30]).

Following is an overview of selected airway devices aimed to set the context in which the Baska mask can be evaluated.

1.3.1. The Face Mask

The face mask is the mainstay of airway management. It consists of a dome-shaped transparent plastic unit designed to cover the patient's nose and mouth. There is a 22 mm female connector (15 mm male connector in paediatric masks) at the top end and a cuff encircling the base (Figure 1.3). It is designed in a way that allows a reasonable airway seal to be achieved between the patient's face and an anaesthetic circuit [24].

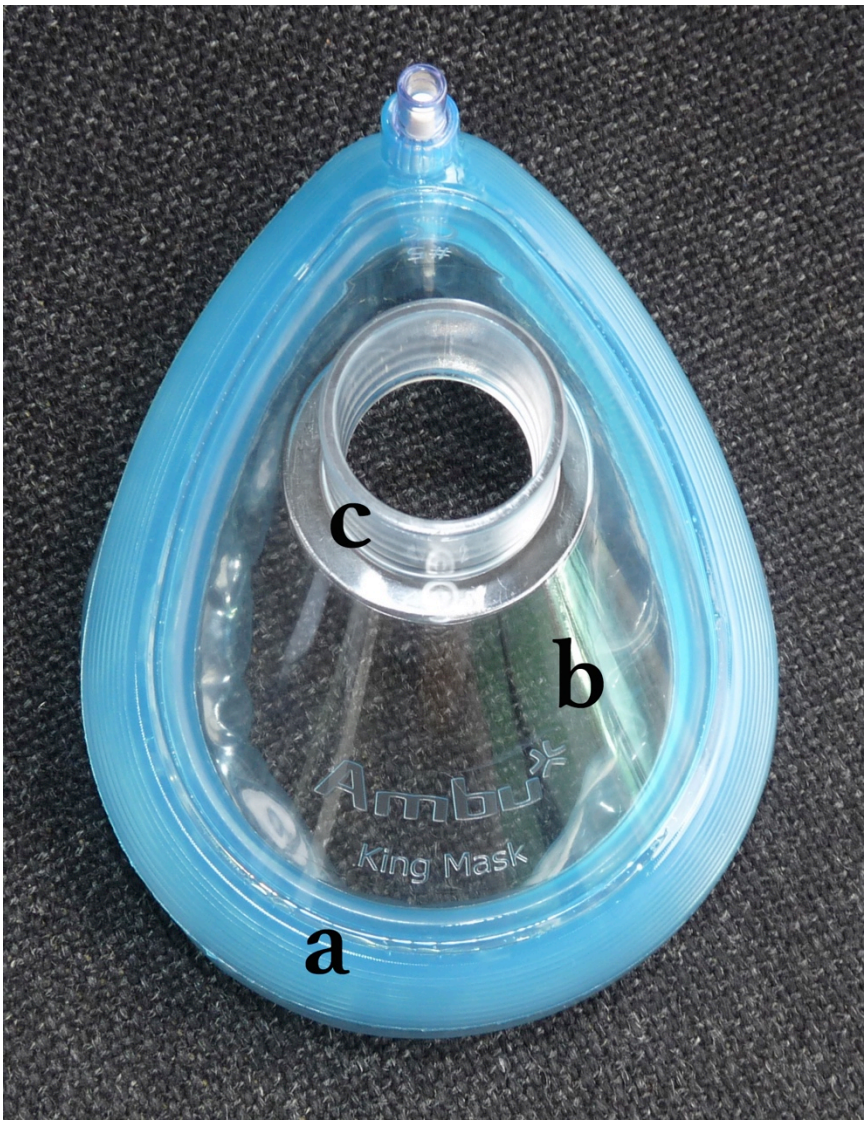

Figure 1.3. The face mask

(Ambu® AS, Ballerup, Denmark. Image by V. Alexiev)

Note: a – mask cuff; **b** – dome; **c** – anaesthetic circuit connector.

The face mask is readily available in all clinical areas, including non-critical areas such as hospital wards, outpatient departments etc. Most staff are familiar with its use to certain extent, it does not require additional equipment for placement, and is non-invasive.

Significant skill is required to use the face mask appropriately and the device has a relatively long learning curve. Komatsu et al. report that 14 out of 15 interns achieved 80% success rate at mask ventilation after a median of 25 procedures [31]. The operator usually maintains the mask position and the airway patency manually thus is restricted in performing other tasks. The face mask does not provide a separation between the orogastric and airway pathways. Certain patient categories often pose a challenge, for example edentulous or bearded patients [32]. The airway patency is achieved by using continuous manoeuvres, which can be unreliable and physically challenging; oropharyngeal airway insertion may be required. Failure to achieve a good airway seal and airway patency may result in an inability to ventilate the patient.

1.3.2 The Cuffed Endotracheal Tube

The cuffed endotracheal tube (ETT) is the gold standard in securing the airway [24]. It consists of a plastic tube that is passed via the patient's mouth or nose into the trachea (Figure 1.4). The proximal end features 15 mm male connector for attachment to an external breathing circuit. The distal end incorporates an inflatable cuff.

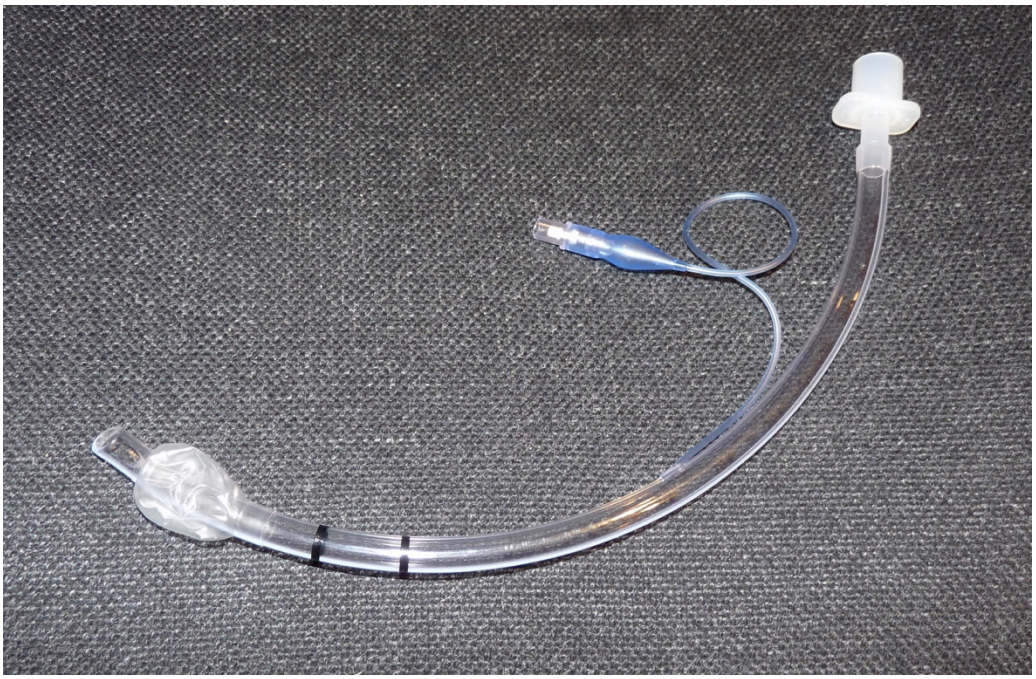

Figure 1.4. The cuffed endotracheal tube
(Covidien llc, Mansfield, MA, USA. Image by V. Alexiev)

The cuffed distal end of the endotracheal tube is placed in the tracheal lumen. On cross-section the tracheal lumen has oval or lunate shape [33]. Accordingly, a good fit of the ETT cuff against the tracheal wall should be easily achievable as long as a device of appropriate size is selected. The cuffed ETT consistently demonstrates an excellent airway seal [34], protects the lungs from aspiration and allows for ventilation using higher airway pressures [24]. It is not easily displaced, when properly secured, thus being the airway management method of choice for prone position surgery. It is estimated that approximately 40% of the general anaesthetics in UK are delivered via an ETT [35].

The airway seal of the cuffed ETT is a function of multiple factors, e.g. the cuff resting volume and length, the cuff wall thickness, the relationship between the cuff perimeter with that of the trachea [36, 37]. Furthermore, the clinical utility of the highest achievable airway seal is limited as cuff pressures above 25-30 cm H_2O might affect the tracheal mucosa blood flow resulting in tissue ischaemia and tracheal morbidity [38, 39].

While the cuffed ETT provides protection from aspiration intraoperatively there is concern of post-extubation laryngeal dysfunction [40]. This may result in reduced airway protection in the postoperative period.

The placement of ETT requires significant skill and additional equipment, and the learning curve is relatively long. Komatsu et al. report that 9 out of 15 interns achieved 80% intubation success rate after a median of 35 procedures, and Mulcaster et al. suggest that success rate of 90% is achieved after 50 or more intubation attempts [31, 41]. Furthermore, skill retention may be an issue [42], given the major shift towards use of SADs [43]. The incidence of side effects (e.g. sore throat, hoarse voice, dysphagia) is high [29, 44]. Some complications are potentially devastating (e.g., oesophageal intubation, tracheal perforation) [45, 46]. Nevertheless, the ETT is the 'gold standard' device for airway management in the unconscious/anaesthetized patient, and proficiency with device insertion is a mandatory skill for health professionals involved in advanced airway management.

1.3.3. The Supraglottic Airway Devices

The face mask and the ETT illustrate two approaches in managing the patient's airway: external and infraglottic. The patient's pharynx offers an alternative. The supraglottic airway devices (SADs), also called extraglottic airway devices or supralaryngeal airways, provide an airway conduit between the mouth opening and the supraglottic pharyngeal space. Examples include the oropharyngeal airway, the laryngeal mask airway, the i-gel® and the object of this work – the Baska™ mask. Most SADs separate, to a limited extent, the orogastric and airway pathways, while sparing the trauma of instrumentation of the larynx and the trachea. Some devices have an integrated conduit to drain gastric liquid contents should some be regurgitated.

A list of advantages and disadvantages of the SADs as compared with the ETT is presented in Table 1.2. When compared with the ETT, the SADs as a group appear to be easier to master and to use [31, 47, 48], they have good insertion success rates [49, 50], ancillary equipment is not required for their placement, most of them provide sufficient airway seal to permit positive pressure ventilation [51-53], and have low incidence of side effects [29, 54, 55]. Not surprisingly SADs are the most popular class of airway devices used in patients undergoing elective surgery where the risk of aspiration of gastric contents is low [43]. Patients managed with SADs may have lower anaesthetic requirements in comparison with those in whom ETT is placed [47]. The airway resistance is higher after ETT use as compared to SADs, which may be related to laryngeal soft tissue swelling after endotracheal intubation as demonstrated by Tanaka et al. [56]. The fact that no additional equipment is required to place SADs, the lower anaesthetic requirement to ensure airway device tolerance, the lower incidence of postoperative complications and the increased speed of patient turnover is likely to reduce the cost of care delivery.

Table 1.2. Comparison of the SADs with the ETT (see Note 1)

Advantages of the SADs over the ETT:

Less invasive

Faster learning curves

No need for additional insertion equipment

Better haemodynamic stability at insertion and emergence

Lower anaesthetic requirement for airway tolerance

Less increase in the intraocular pressure after insertion

Lower incidence of laryngospasm on emergence

Lower incidence of postoperative complications (e.g. sore throat, cough)

Better oxygen saturation on emergence

May facilitate fibreoptic endotracheal intubation

Increased case turnover

Advantages of the ETT over the SADs:

Higher airway sealing pressure

Better protection from aspiration (see Note 2)

Instances where conclusions cannot be drawn due to limited data:

Risk of regurgitation

Incidence of PONV

Note 1: Summary based on the work of Brimacombe [47], Yu and Beirne [54] and Uppal et al [34] and applies to the LMA-type devices and the i-gel®.

Note 2: The value of the available data regarding the incidence of aspiration of gastric contents is limited as the SADs are mostly used in lower-risk patients and procedures, and the event per se is rare.

The SADs have some common and specific disadvantages. Firstly, none of them provides the level of airway protection from gastric contents than can be obtained with an endotracheal tube [24]. The quality of the airway seal achieved is device specific, e.g. increasing in the order: LMA Classic™, LMA Supreme™ and Baska™ mask [51-53]. Accordingly, these devices will perform differently should a need for ventilation with high airway pressures arise. SADs are designed to fit in an area variable in terms of shape, size and muscle tonus, and there will be patients in whom they will fail [23, 57]. This may result in major patient morbidity and mortality [30, 57].

The selection of SADs described in the following pages is by no means complete. It rather illustrates the evolution of this class of devices and highlights important design characteristics and specific device advantages and disadvantages. SADs differ in many ways: by sealing site (base of tongue, peri-laryngeal); by sealing mechanism (none, inflatable cuff, non-inflatable cuff, self-energising cuff); by availability of drainage systems (oesophageal drainage channels, sump reservoir); by material from which the device is made (silicone, polyvinyl chloride, latex etc.) [23].

It is estimated that over 50% of the general anaesthetics in UK are delivered with SADs, the majority with an cLMA, i-gel® or LMA ProSeal™ [30]. While the experience with them is largely reassuring, major complications, including aspiration, do occur [30, 58]. To prove the superiority of one airway device over another in terms of protection from aspiration is difficult given the low incidence of such events. For example, the incidence of aspiration with cLMA is estimated to be 0.02% [59]. While the cuffed ETT is believed to provide the highest level of protection from aspiration [24], the disadvantages associated with its use (e.g. technically challenging insertion, need for airway instrumentation, high incidence of patient discomfort postoperatively, etc.) led to decrease in its use and increased preference for SADs. Improvements in the quality of the airway seal and the efficiency of the oesophageal drainage systems of SADs would be expected to increase the safety of these devices.

1.3.3.1. The Oropharyngeal Airway

Arthur Guedel described the oropharyngeal airway (Guedel airway) in 1933 [19]. It is inserted via the mouth opening and consists of a curved rigid airway conduit that follows the course of the natural airway pathway in the oral cavity and the pharynx (Figure 1.5).

Figure 1.5. Guedel airways

(Intersurgical Ltd., Wokingham, UK. Image by V. Alexiev)

Note: a – curved airway conduit; **b** – pharyngeal orifice; **c** – bite block; **<** - external orifice.

While the Guedel airway has an integrated airway channel, it also acts as a bite block, prevents the tongue from depressing the epiglottis, and prevents the pharyngeal soft tissues from obliterating the pharyngeal space above the glottic opening.

The oropharyngeal airway can be used as a stand-alone device, or in a tandem with a face mask. It does not require extra equipment for insertion (though a tongue depressor may be used). Size selection is very simple, based on patient's facial surface anatomy observation; no calculations, charts, numerical knowledge nor measurement with additional devices is required. In order for this device to be tolerated the patient has to have significantly depressed level of consciousness. The Guedel airway may provoke gagging, vomiting and laryngospasm. The lower airway is not protected and aspiration is a significant risk. Teeth and oropharyngeal soft tissue injury is possible [24].

The Guedel airway does not itself provide an airway seal. To address this Beverley Leech designed the Pharyngeal bulb gasway (or the Leech airway) in 1937 [20]. The airway seal is at the base of the tongue rather than peri-laryngeal.

1.3.3.2. The Laryngeal Mask Airway

The Laryngeal Mask Airway® (LMA®) was invented by Archie Brain [22, 25]. While working as anaesthetist in London, he developed an interest in the upper respiratory tract and started work on an airway device (a laryngeal mask) that would cover the laryngeal inlet and connect it to an external breathing system. Using anatomical specimens, Dr. Brain developed multiple device prototypes aiming to achieve good fit around the glottic inlet, adequate airway seal, and dimensions that would allow for easy device insertion. The first time the new device was used was in 1981 on a patient undergoing an inguinal hernia repair. The device was inserted blindly, provided an effective airway and a seal around the laryngeal inlet that allowed manual ventilation, and the patient did not have throat pain postoperatively. While the first clinical study on 23 patients in 1982 confirmed the device's potential, further design refinements were required to improve the device performance [22, 25]. Dr. Brain continued his work using cadavers as well as clinical testing. In patients in whom the device malfunctioned, he utilised direct laryngoscopy to explore the possible causes. Subsequently, he used fibreoptic imaging to explore the device behaviour in situ [25]. Following extensive research and modifications the finalised device – the LMA Classic™, was launched in 1987. The device offered significant benefits (easy blind insertion, reliable performance, improved patient comfort) and rapidly became popular. Within 3 years it was used in over two million patients [25]. The use of an LMA as an airway rescue device in the "can't ventilate" scenario was recommended in the 1993 American Society of Anesthesiologists (ASA) difficult airway algorithm [60].

The reusable LMA Classic™ consists of a mask with silicone cuff, designed to provide airway seal around the glottis, and a stem connecting this mask to an external ventilation system. The LMA Unique™ (Figure 1.6) is a single-use version of the LMA Classic™ aimed at reducing cost and infection transmission risk [61]. The cuff is made of polyvinyl chloride.

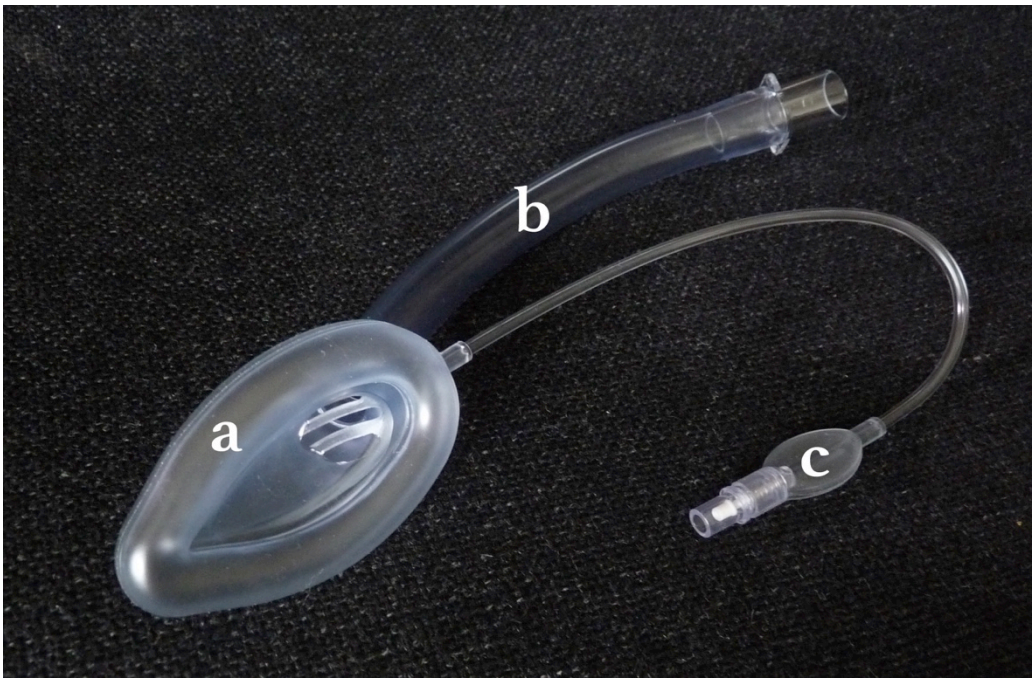

Figure 1.6. The LMA Unique™

(Teleflex Medical, Athlone, Ireland. Image by V. Alexiev)

Note: a – device cuff; **b** – stem with airway channel; **c** – cuff inflation valve

The LMA eliminates or reduces some risks associated with ETT use (e.g. the risk of oesophageal intubation, damage to the laryngeal structures or the trachea) while separating the airway and the gastrointestinal tract at the pharyngeal level. The LMA has a short learning curve [48], and reported success rates of up to 99% [62]. Insertion does not require additional equipment. The incidence and severity of patient discomfort (e.g. sore throat, hoarseness, dysphagia) postoperatively attributed to LMA use is significantly lower as compared with the ETT [47, 63].

Nevertheless the LMA has its limitations. Unlike the ETT it does not protect the lower airway from aspiration [24]. Compared to the ETT, the LMA Classic™ and the LMA Unique™ provide an inferior airway seal of approximately 20 cm H_2O [51, 64]. The LMA cuff may compromise the blood flow in its proximity, causing tongue swelling, as well as an injury to the lingual, hypoglossal and recurrent laryngeal nerves [65-67].

Variations of the LMA were developed to address particular clinical needs (e.g. the LMA Flexible™, LMA Fastrach™, LMA Supreme™, LMA Unique™) and some are discussed below. A pilot cuff valve was added to various LMA versions to address concerns of cuff over-inflation [68].

The LMA Flexible™ (Figure 1.7) has a reinforced flexible tube with smaller lumen [69] and is intended for use in ENT, dental and maxillofacial surgery.

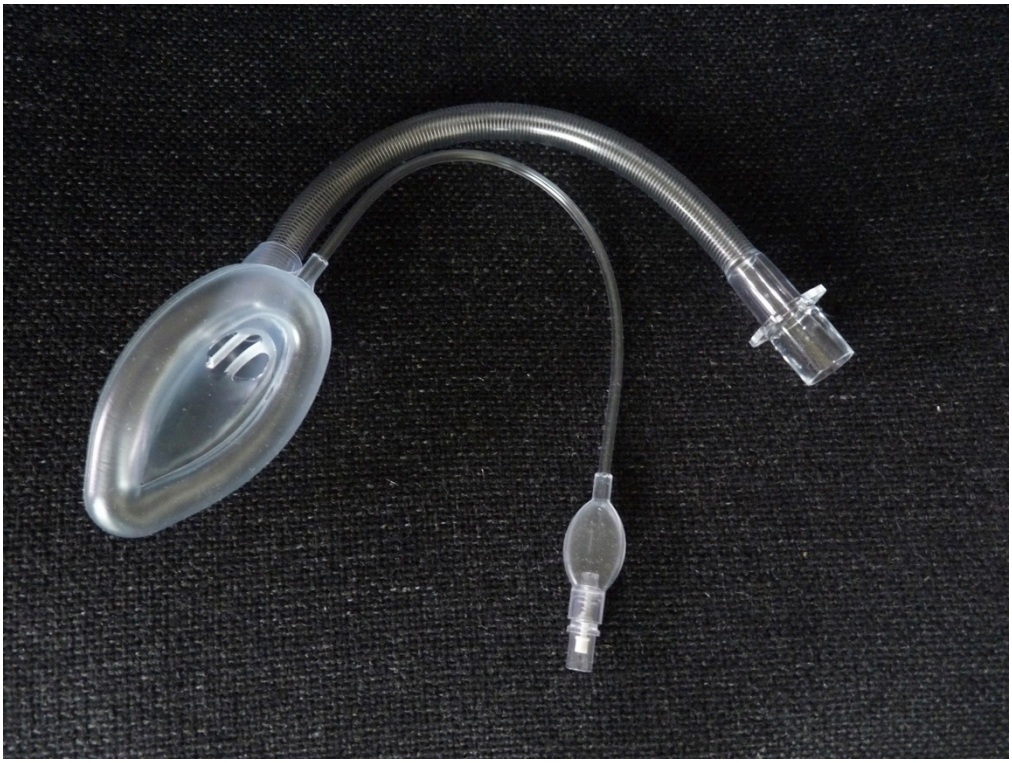

Figure 1.7. The LMA Flexible™
(Teleflex Medical, Athlone, Ireland. Image by V. Alexiev)

The LMA Fastrach™, also called Intubating LMA (Figure 1.8), has a larger lumen allowing for the blind or fibreoptic insertion of a custom made cuffed endotracheal tube [70, 71].

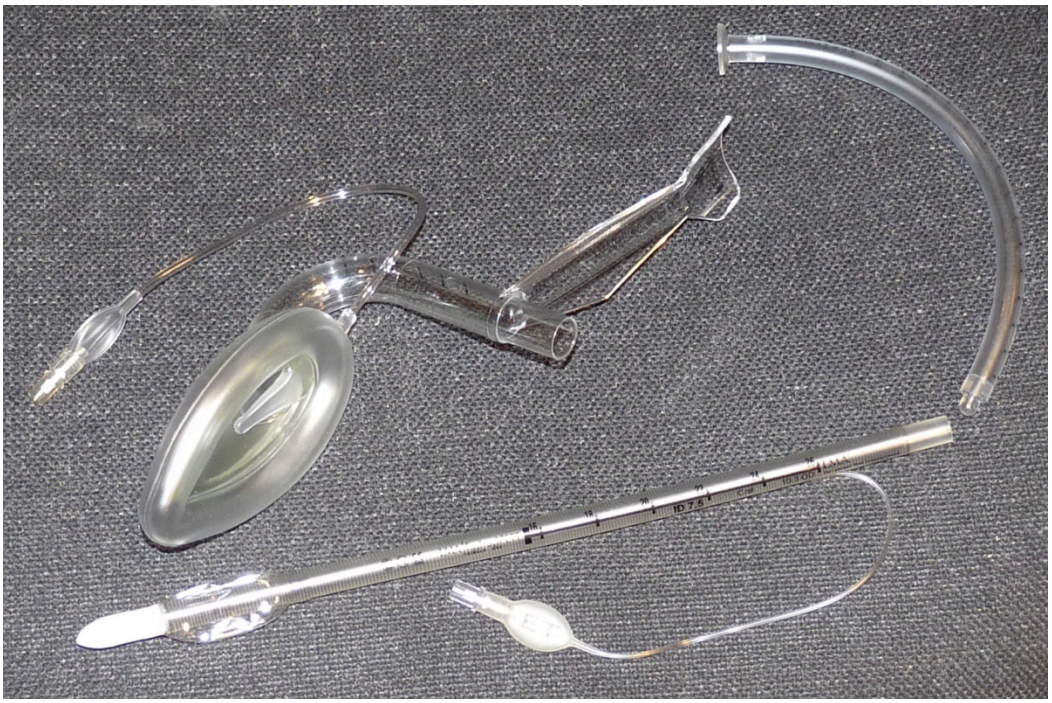

Figure 1.8. The LMA Fastrach™
(Teleflex Medical, Athlone, Ireland. Image by V. Alexiev)

The LMA ProSeal™ and its single use successor the LMA Supreme™ (Figure 1.9) deliver improved airway seal above 25 cm H_2O [52, 72-74]. Both devices incorporate an oesophageal drainage channel aiming to reduce the risk of insufflation of air into the stomach, and the risk of lung aspiration of regurgitated gastric liquid [75, 76].

Figure 1.9. The LMA Supreme™

(Teleflex Medical, Athlone, Ireland. Image by V. Alexiev)

Note: < - oesophageal drainage channel orifice at the cuff tip.

Case reports describe a rare dysfunction of the drainage channel due to posterior folding of the cuff tip resulting in gastric insufflation during positive pressure ventilation [77, 78].

1.3.3.3. The i-gel®

The i-gel® (Figure 1.10) was developed by Muhammed Aslam Nasir over almost 20 years and launched in 2007 [79, 80]. It is a peri-laryngeal sealer with non-inflatable cuff made of thermoplastic elastomer, aiming to reduce the risks associated with inflatable cuff use.

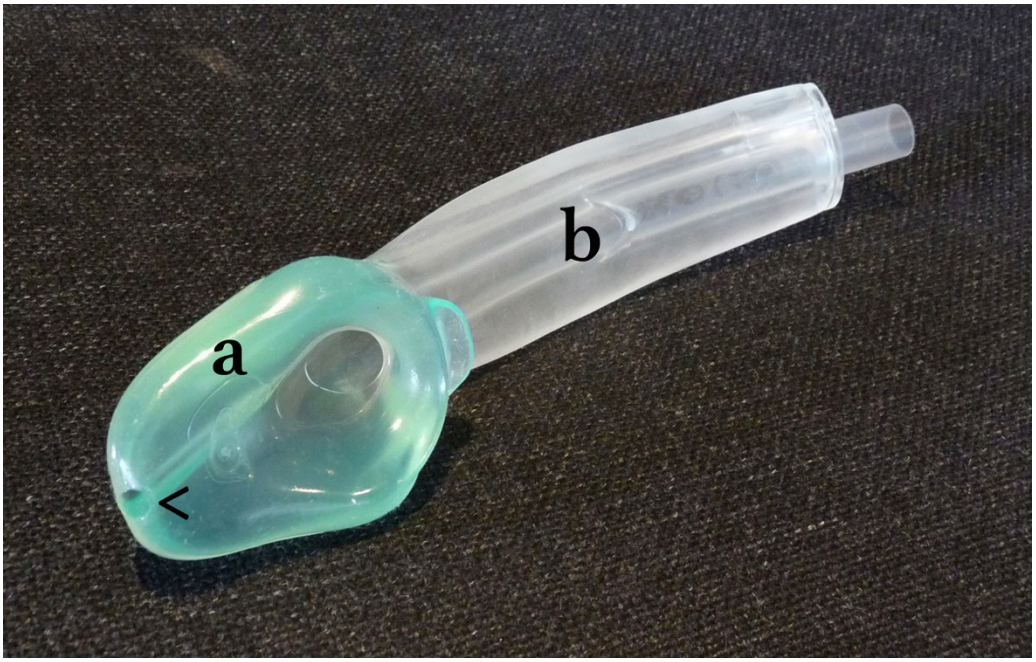

Figure 1.10. The i-gel®
(Intersurgical Ltd., Wokingham, UK. Image by V. Alexiev)

Note: a – device cuff; **b** – device stump incorporating an airway channel and a drainage channel; **<** - oesophageal drainage channel orifice

Inadvertent LMA cuff overinflation has been shown to be associated with increased incidence of throat discomfort postoperatively [81]. The risk of cuff overinflation does not exist with the non-inflatable i-gel® cuff. The cuff pressure exerted by the i-gel® on the adjacent pharyngeal tissues was shown to be comparable to that of the LMA Supreme™ when the LMA intra-cuff pressure was confirmed to be within the recommended limit of 60 cm H_2O [74].

The i-gel® airway leak pressures have been reported to be 23-32 cm H_2O [50]. This indicates an airway seal better than that of the LMA Unique™ [51] and comparable with that of the LMA ProSeal™ and Supreme™ [50, 52, 82]. The incidence of complications (e.g. the incidence of postoperative throat discomfort is below 10%) appears to be comparable or better than that of the LMA-class of devices [49, 83, 84].

The i-gel® has an oesophageal drainage channel aiming to reduce the risks associated with gastric liquid regurgitation. Schmidbauer et al. compared the oesophageal seal of the i-gel® with that of other SADs [85]. They concluded that the i-gel® had inferior oesophageal seal yet was able to drain effectively regurgitated fluid during simulated vomiting.

The overall insertion success rates of i-gel® have been shown to be above 95% and comparable to the LMA-type devices [51, 52, 86, 87]. Some early trials show lower success rates which has been attributed to a lack of operator experience and suboptimal device sizing guidelines [82, 88]. There is conflicting evidence regarding the performance of the i-gel® in the hands of inexperienced users. Wharton et al. published results indicating that i-gel® has favourable profile in the hands of novice users [89]. In contrast, Ragazzi et al. compared the i-gel® with the LMA Supreme™ and concluded that the latter may be preferable in emergency airway management by novices, with higher first and overall insertion attempt success rates and better airway seal [73].
The use of SADs with inflatable cuff in the aeromedical and hyperbaric environment carries the risk of gas expansion within the device cuff, due to the pressure-volume relationship. In such settings the use of i-gel® offers obvious advantages [23].

1.3.3.4. The Cuffed Oropharyngeal Airway (COPA™)

The Cuffed Oropharyngeal Airway (COPA™) was invented by Robert Greenberg in 1992 [90]. The COPA™ builds on the concept of the Guedel airway and the Pharyngeal bulb gasway [19, 20]. This disposable SAD consists of an airway channel surrounded by an inflatable cuff. The distal end of the airway channel opens below the cuff, close to the glottic opening. The proximal end features standard male 15 mm anaesthetic circuit connector. The COPA™ cuff sits in the pharynx above the larynx providing an airway seal at the tongue base, displaces the tongue anteriorly and elevates the epiglottis. The sizing method, as that for the Guedel airway, is based on external facial anatomy landmarks [90].

In clinical studies, the COPA™ has been demonstrated to have a lower first time and overall success rate, worse airway stability, an airway seal lower than that of the LMA Classic™ and higher incidence of complications [49]. Given the low seal pressure COPA™ is of questionable value if positive pressure ventilation is required. The cuff of the COPA™ does not separate the entrance of the larynx from the oesophageal one thus gastric insufflation and/or aspiration is possible. All above suggests that the LMA Classic™ is superior to the COPA™.

1.3.3.5. The Combitube®

The principle on which the Combitube® (oesophageal tracheal double-lumen airway) functions was described by Michael, Lambert and Mehan in 1968 [91]. The device was introduced by Michael Frass in 1987 [92]. It consists of a double lumen tube and two inflatable cuffs (Figure 1.11). The proximal lumen opens between the two cuffs, and the distal lumen opens below the lower cuff.

Figure 1.11. The Combitube®

Note: Edited image. Original picture downloaded from pixabay.com and used under the Creative Commons CCO licence.

The device is advanced blindly via the mouth and the pharynx. Usually it enters the oesophagus. In this case it functions in a manner similar to the COPA™. Ventilation is performed via the proximal lumen and the airway seal is effected by inflating the upper cuff at the level of the tongue base. In the rare case when the tube enters the trachea the Combitube® functions like an endotracheal

tube. Airway seal is achieved by inflating the distal cuff endotracheally and ventilation is provided via the distal lumen.

The main theoretical advantage of the Combitube® is the simple blind insertion not requiring ancillary equipment. Unfortunately real life use was shown to be associated with a significant incidence of major complications including pharyngeal, vocal cord and tracheal injury, pneumothorax, oesophageal perforation, mediastinitis, and aspiration of gastric contents [93-97]. Structural damage to the upper airway, oesophagus and trachea was likely contributing to the aforementioned complications. A cadaveric study demonstrated that an oesophageal insertion of a Combitube® resulted in anterior bulging of the oesophagus and the trachea; the inflation of the distal cuff of the device resulted in distension of the oesophagus; and lacerations in the oesophageal mucosa were detected after the device was removed [98]. Furthermore, blind device insertion by non-experts and device cuff overinflation may have contributed to the high incidence of complications in the prehospital setting.

1.4. The Baska™ Mask

1.4.1. Device description

The Baska™ mask is a new SAD developed by Kanag Baska, an anaesthetist, and his wife Meenakshi Baska, a general practitioner, from Sydney, Australia. Its proposed advantages include superior airway seal, reduced pressure on the surrounding tissues, and improved drainage system for regurgitated gastric content. The device has the standard configuration of a laryngeal mask connected to an airway conduit stem, with many novel features (Figure 1.12).

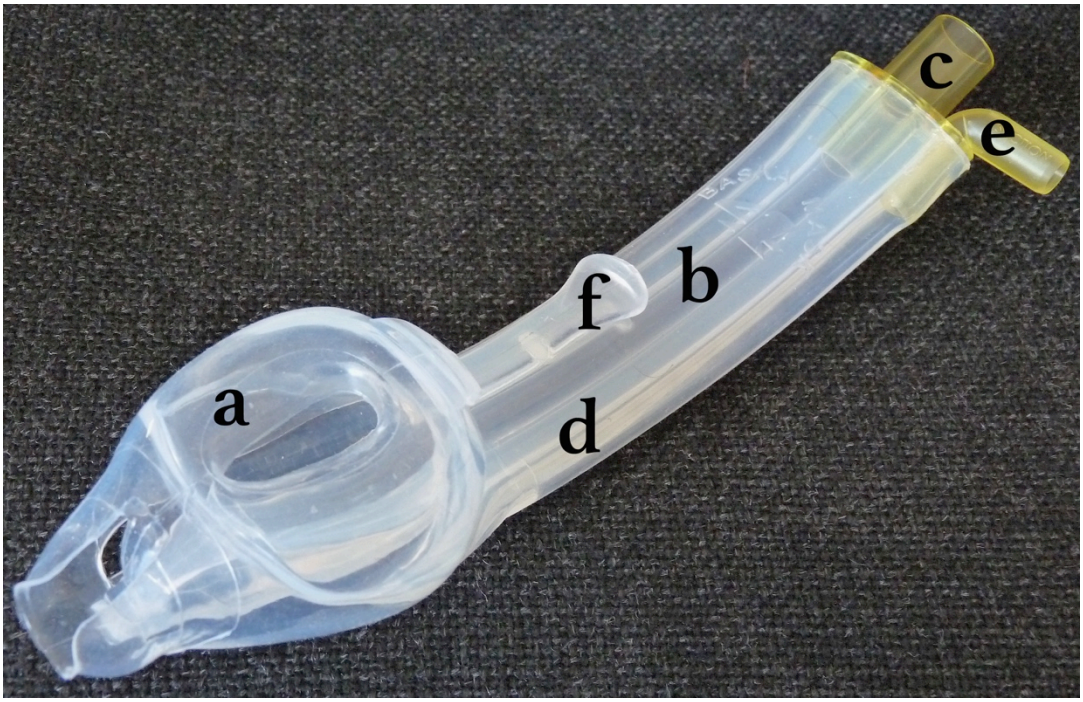

Figure 1.12. The Baska™ mask
(Logikal Health Products PTY Ltd, Morisset, Australia. Image by V. Alexiev)

Note: a – device cuff; **b** – central airway channel; **c** – ventilator circuit connector; **d** – side suction channels (one on each side); **e** – suction connector; **f** – tab to flex the device during placement.

The Baska™ mask cuff (Figure 1.13) consists of a non-inflatable silicone membrane. The lateral rim of the membrane maintains the mask shape. The medial part surrounds the laryngeal inlet and maintains contact with the peri-laryngeal structures (Figure 1.14).

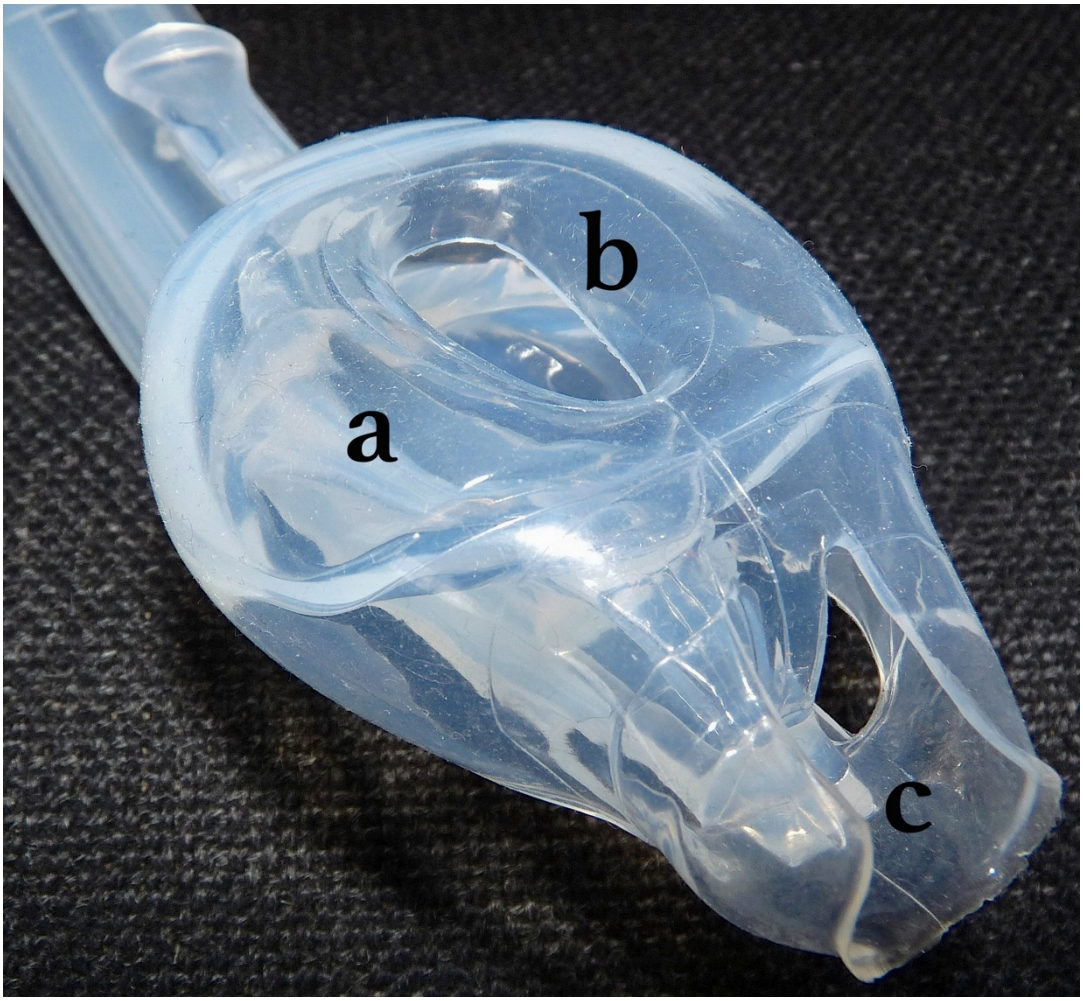

Figure 1.13. The Baska™ mask cuff (anterior view)

Note: a – peripheral (lateral) thicker part of the cuff membrane, it maintains the cuff shape; **b** – central (medial) thinner part, folds around the laryngeal inlet; **c** – oesophageal orifice of the mask drainage system. Image by V. Alexiev

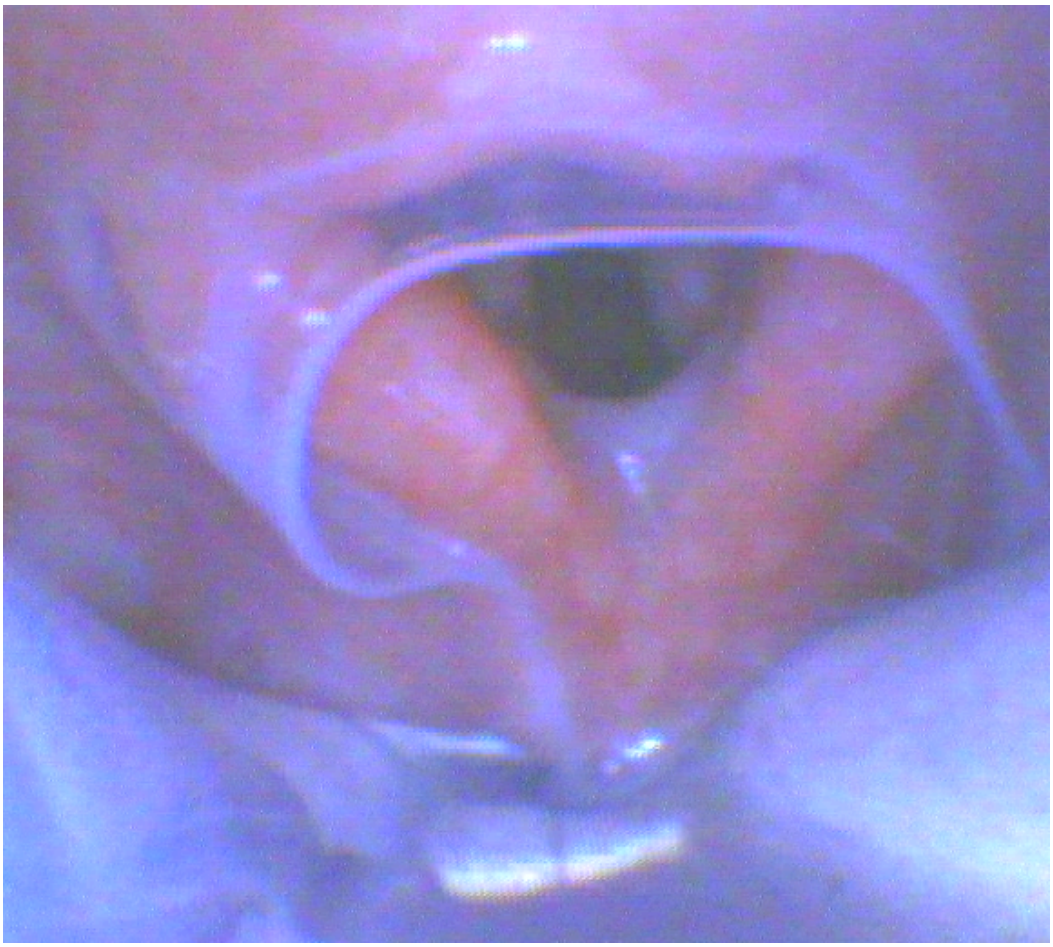

Figure 1.14. Fibreoptic view of the Baska™ mask cuff approximating the laryngeal inlet.

Note: Details regarding the laryngeal inlet anatomy and the interactions of the Baska™ mask cuff and the larynx are provided in **Figure 1.2**, respectively **Chapter 7**. Image by V. Alexiev

The proposed advantages of this non-inflatable pre-shaped design include reduced pressure on the soft tissues and a superior airway seal. The Baska™ mask features a novel concept - intermittently enhanced airway seal [23]. This is achieved by a cuff responsive to changes in the airway pressure. There is an increase in the airway pressure during positive pressure inspiration. This might improve the contact between the cuff membrane and the adjacent soft tissues, thus enhancing the airway seal.

The posterior and inferior aspect of the mask features a drainage system. The distal tip of the device has an oesophageal opening (Figure 1.13), connected to pharyngeal drainage sump reservoir at the back of the mask (Figure 1.15). The latter is drained via two suction channels (Figure 1.12).

Figure 1.15. The Baska™ mask cuff (posterior view)
(Image by V. Alexiev)

The sump reservoir is connected to two drainage canals. They run on both sides of the airway canal along the mask stem and open on the top of it (Figure 1.12). One can be connected to an active suction system; the other remains open to the atmosphere. The sump reservoir features two grooves on the posterior aspect of the mask (Figure 1.15). This design may allow regurgitated fluid to escape into the upper pharynx above the mask in case the drainage canals above get blocked, instead of soiling the lower airways.

The device stem has an airway canal in the middle flanked by the drainage canals and acts as a bite-block. The airway canal may allow passage of a fibreoptic scope and appropriately sized ETT thus an attempt at intubation via the Baska™ mask might be possible. The stem features a tab in the front to facilitate device manipulation during insertion (Figure 1.12).

1.4.2. Instructions for Use

Following device integrity check water soluble lubricant should be applied on the front, lateral and posterior aspects of the mask. The head of the patient should be in a neutral position. The proximal part of the mask should be compressed between the thumb and the index and middle finger. The mask is advanced along the hard palate into the pharynx. The device tab can be pulled to help the mask negotiate the palato-pharyngeal curve. The mask is advanced further until resistance is felt. A breathing circuit is connected and positive pressure ventilation is applied.

Gastric tubes should not be passed via the drainage system. Suction can be connected to the device suction port at the end of one of the drainage channels as needed. The vent at the end of the other drainage channel should remain open at all times.

Continuous suctioning during the anaesthetic should be avoided as the resulting airflow may dry the mucous membranes and predispose the patient to sore throat.

1.4.3. Prior Work

Apart from personal communication from the Baska™ mask inventors there were no independent clinical trials or any other clinical data available at the inception of the work on our project. We wished to perform series of studies to evaluate the performance and safety profile of this novel device.

1.5. Airway Device Evolution

A key long-standing trend in airway management appears to be a reduction in invasiveness - from tracheotomy via oropharyngeal intubation towards today's widespread use of SADs. Within the SAD group areas of increased interest proved to be: quality of the airway seal; pressure of the device cuff on the surrounding tissues; and regurgitated gastric content drainage systems. Concerns regarding communicable diseases including prions led to a major shift towards disposable equipment use [23]. There is increasing awareness of the long-term effects of common chemicals (e.g. phthalates contained in polyvinyl chloride) in our environment [99, 100]. The compounds used in today's airway devices will likely be subject to increasing scrutiny.

The learning curve, ease of use, insertion success rates, overall performance and safety profile are major determinants of the success (or failure) of new devices. Yet we have to be careful not to prematurely dismiss valuable ideas and features. The history of development of successful devices has often been very long and required iterative product modification and refinement. Relatively minor device modifications may convert a ‘failed’ device into a successful and widely used one. For example, in the first study of the laryngeal mask, the airway seal pressures achieved in male patients were suboptimal [22] and this was addressed with improved device design [25]. The refinement of the design, the development of sizing guidelines and best use techniques requires patience and persistence.

2. Aims and Hypotheses

2.1. Aims

2.1.1. Overall Aim

To evaluate the performance and safety profile of the Baska™ mask, a novel supraglottic airway, in low-risk adult and paediatric patients.

2.1.2. Specific Aims

2.1.2.1. To conduct a first in humans clinical study to determine Baska™ mask insertion success rates, to evaluate the quality of the airway seal and monitor complication rates in adult female patients.

2.1.2.2. To evaluate the learning curve for this novel device.

2.1.2.3. To compare the Baska™ mask to an established supraglottic airway device, namely the single-use classical laryngeal mask airway comparing the device insertion success rates and the quality of the airway seal in adult female patients.

2.1.2.4. To evaluate the effectiveness of the Baska™ mask manufacturer's sizing guidelines in adult male patients.

2.1.2.5. To conduct a first in children clinical study of the Baska™ mask, evaluating the device insertion success rates, quality of airway seal and safety profile in paediatric patients.

2.1.2.6. To characterize the behaviour of the Baska™ mask in the pharyngeal cavity using fibreoptic evaluation.

2.2. Hypotheses

2.2.1. Overall Hypothesis

That the Baska™ mask would prove safe and effective as a supraglottic airway in both adults and children, and would perform comparably to the classic Laryngeal Mask Airway (cLMA) in patients undergoing low risk elective surgery.

2.2.2. Specific Hypotheses

2.2.2.1. The Baska™ mask would have comparable overall insertion success rates to the cLMA and provide for effective and safe airway in adult female patients.

2.2.2.2. The Baska™ mask would have a short learning curve.

2.2.2.3. In adult female patients the Baska™ mask would have an airway seal superior to the single-use classical Laryngeal Mask Airway device. In adult female patients the Baska™ mask would have first-time insertion success rate comparable to that of the single-use classical Laryngeal Mask Airway device.

2.2.2.4. In adult male patients the manufacturer's Baska™ mask sizing guidelines would correlate well with the size of the device used successfully.

2.2.2.5. The Baska™ mask would have satisfactory overall insertion success rates and provide for effective and safe airway in paediatric patients.

2.2.2.6. The Baska™ mask would have a good alignment with the peri-laryngeal structures.

3. An Observational Study of the Baska™ Mask in Low-Risk Female Patients

3.1. Introduction

The Baska™ mask is a new supraglottic airway device (Chapter 1, Section 1.4). As described in detail in chapter 1 (section 1.4.1), it has a cuff consisting of non-inflatable silicone membrane (Figures 1.13 and 1.14). Proposed advantages include an improved airway seal and reduced tissue trauma. A novel drainage system is aimed at improving the clearance of pharyngeal secretions and reducing the risk of aspiration (Figure 1.15).

The performance and safety profile of the Baska™ mask in the management of the airway was unknown. In this study we aimed to perform a pilot evaluation of the Baska™ mask in low risk female patients undergoing anaesthesia for ambulatory (mainly gynaecologic) surgical procedures. Our objective was to accumulate initial information regarding the device insertion, learning curve, intraoperative performance, and the type and incidence of complications. Our hypothesis was that the Baska™ mask would have comparable overall insertion success rates to the cLMA and provide an effective and safe airway in adult female patients. The primary outcomes assessed were the overall device insertion success rate and the airway leak pressure. The secondary outcomes included duration of device insertion, device difficulty scores, airway stability, patient comfort indices and incidence of complications.

The results of this study have been published in the following paper:
Alexiev, V., Salim, A., Kevin, L.G., Laffey, J.G., An observational study of the Baska™ mask: a novel supraglottic airway. Anaesthesia. 2012 Jun; 67(6): p.640-645

3.2. Methods

3.2.1. Patient Selection

Approval from the Galway University Hospitals Research Ethics Committee was obtained (Ref. C.A. 621). Following written informed consent we studied 30 female patients of ASA physical status 1-3 aged 18 years or older, deemed to be at low risk of difficult tracheal intubation. The inclusion and exclusion criteria are shown in Table 3.1.

Table 3.1. Study inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
▪ ASA physical status 1-3 ▪ Age 18-65 ▪ BMI 20-35 $kg.m^{-2}$ ▪ Non-urgent surgery of planned duration ≤ 2 hrs.	▪ Patients unwilling or unable to give consent ▪ Neck pathology ▪ Previous or anticipated problems with the upper airway or the upper gastrointestinal tract ▪ Live pregnancy ▪ Increased risk of gastric aspiration

3.2.2. General Anaesthesia

Standardised general anaesthetic was provided [101, 102]. Standard monitoring was commenced, including ECG, non-invasive blood pressure, pulse oximetry and end-tidal gas monitoring. Fentanyl (1-1.5 $\mu g.kg^{-1}$) was given intravenously. A sleep dose of propofol (2.5-0 4.0 $mg.kg^{-1}$) was titrated to induce anaesthesia and ensure jaw relaxation. Manual ventilation was commenced with sevoflurane (2.0-4.5%) in oxygen.

3.2.3. Baska™ Mask Insertion

One investigator (VA) with over 10 years of clinical experience (but less than 10 prior insertions of the Baska™ mask) performed all device insertions, in accordance with the manufacturers' instructions [32]. Up to 3 Baska™ mask insertion attempts were permitted per patient. During the first attempt the Baska™ mask size choice was based on the patient's weight as per manufacturer's instructions (Table 3.2).

Table 3.2. Manufacturer guidelines for Baska™ mask size selection

Patient weight	Recommended Baska™ mask size
30 - 50 kg	Size 3
50 - 70 kg	Size 4
70 -100 kg	Size 5
>100 kg	Size 6

If the device did not function properly the following manipulations were performed in sequence: the device was pushed further in, rotated and then withdrawn slightly. If an effective airway was not achieved, the device was removed. If the problem was deemed to be due to a large leak, a device one size bigger was used during the following attempt. If the device was deemed too large, as evidenced by difficulty in advancing it into the pharynx and in ventilating the patient, a device one size smaller was inserted. Following 3 failed insertion attempts, a laryngeal mask airway (LMA) was inserted. If this failed the back-up plan was to secure the airway by means of tracheal intubation.

3.2.4. Maintenance of Anaesthesia

Once the airway was secured with the respective device, mechanical ventilation was maintained until spontaneous ventilation supervened. Anaesthesia was provided with sevoflurane (2.0-4.5%) in a mixture of air and oxygen. Further management was left to the discretion of the primary anaesthetist.

3.2.5. Data Collection

An unblinded independent observer collected all mask insertion - related data. "Duration of device insertion attempt" was defined as the time from the moment the device was touched by the operator until successful ventilation was achieved or the device was removed [103, 104]. "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 [52, 87]. A list of the core device insertion data recorded is shown in Table 3.3.

Table 3.3. Data collected regarding device insertion

Number and duration of insertion attempts
Type and number of additional manoeuvres
Operator - rated ease of insertion on a 10 cm visual analogue scale (VAS)
Presence of leak at 0 and 5 min after mask placement
Airway leak pressure data

3.2.6. Mask Leak Test

A leak test was performed [72, 86, 87]. While the patient was apnoeic, the adjustable pressure-limiting valve was closed to 70 cm H_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 cm H_2O the leak test was immediately interrupted as a safety precaution and a value of 50 cmH_2O was recorded.

The stability of the placement of the Baska™ mask was 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 without pillow. The leak fraction was calculated according to the formula: $[V_{insp} - V_{exp}] / V_{insp} \times 100$.

3.2.7. Data Regarding Device-Related Complications

The following complications were specifically monitored and recorded: arterial oxygen desaturation; lip damage; blood staining on mask removal; and laryngospasm [103, 104]. We evaluated the incidence and severity of throat pain, dysphonia and dysphagia in the recovery room (on arrival and discharge) as well as on the first postoperative day using a 10-point verbal rating scale (VRS).

3.2.8. Sample Size

We planned to recruit a minimum of 20 and a maximum of 50 patients (Figure 3.1). Once 20 patients were recruited an independent observer would determine if the following criteria were fulfilled in five consecutive patients: 1. successful Baska™ mask insertion on first attempt; 2. each insertion of less than 30 s duration; and 3. mean leak fraction less than 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 stopping rules were fulfilled or until 50 patients were recruited, at which stage the study would be terminated.

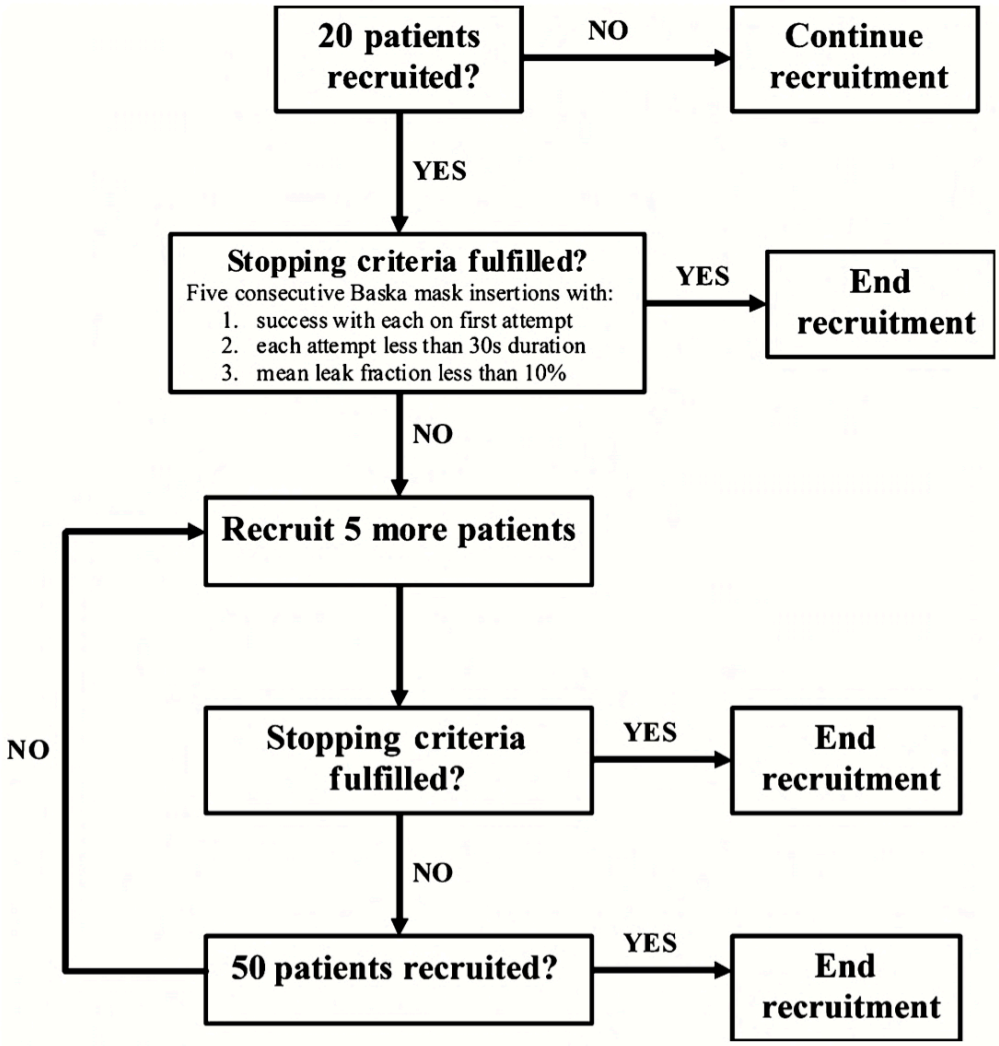

Figure 3.1. Patient recruitment algorithm flowchart

3.3. Results

After 30 patients were recruited the stopping rules were fulfilled and the study was terminated.

3.3.1. Patient Demographics

The patient characteristics are shown in Table 3.4. Our cohort consisted of 30 low risk adult female patients aged 21 to 79 years. The history and airway assessment were not suggestive of difficult intubation and all had Mallampati score below 3. No patient had BMI over 35 $kg.m^{-2}$. 18 (60%) of the patients underwent minor non-laparoscopic gynaecological procedures (e.g. hysteroscopy, curettage, cystoscopy, evacuation of retained products of conception - ERPC), 8 (27%) gynaecological laparoscopies and 4 (13%) had breast surgery. The anaesthetic time was between 8 and 67 minutes.

Table 3.4. Characteristics of the patients enrolled in the study

Number of patients	30
Age; years	47.5 (13.3)
Body mass index; $kg.m^{-2}$	27.6 (4.6)
Patient height; cm	164.5 (7.3)
Patient weight; kg	74.7 (13.9)
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	17 (57%)
2	13 (43%)
3	0
4	0
Type of surgery	
Hysteroscopy/Dilatation and Curettage/ERPC	13 (43%)
Laparoscopy	8 (27%)
Cystoscopy	2 (7%)
Others	7 (23%)

Note: Values are reported as mean (SD), median (IQR [range]) or number (proportion).

3.3.2. Baska™ Mask Insertion and Mask Size

The overall insertion success rate of the Baska™ mask was 96.7% (95% CI 83-100%) [53] (Table 3.5). In one (3%) of the 30 patients an alternative airway device (cLMA) was used. The upper limit of the 95% confidence interval for overall insertion failure rate was 17.2% [105] . In 23 of 30 patients (76.7%, 95% CI 58-90%) the Baska™ mask was placed on first attempt [53]. The upper limit of the 95% confidence interval for first attempt insertion failure rate was 42.3%. The mean (SD) duration of the first insertion attempt was 32.3 (29.8) s, and the mean duration of the successful insertion attempt was 23.9 (13.3) s. The duration of the successful insertion attempt decreased over time as the operator got more familiar with the device, with a mean time 31 (22.5) s for the first 5 patients and a mean time 10.6 (3.4) s for the last 5 patients (Figure 3.2).

A Baska™ mask size 4 was placed successfully in 25 patients with a mean weight 75 (13.7) kg and a mean height 164 (7.5) cm, and a Baska mask size 5 in 4 patients with a mean weight 78.2 (18.3) kg and a mean height 169.5 (6.7) cm.

3.3.3. Baska™ Mask Insertion Difficulty

The mean (SD) operator-rated device difficulty score was 0.9 (1.6) out of 10. There was an indication of a learning effect with the VAS score decreasing from 29.8 (23.6) mm in the first 5 patients to 0.8 (1.1) mm in the last 5 patients (Figure 3.3).

Table 3.5. Anaesthesia management and Baska™ mask insertion data

Overall insertion success rate	29 (97%)
Number of insertion attempts 1 2 3	1 (1-1[1-3]) 23 (77%) 4 (13%) 3 (10%)
Size of Baska™ mask inserted successfully: 4 5 6	 25 (83%) 4 (13%) 0 (0)
Induction of anaesthesia Fentanyl dose: $\mu g.kg^{-1}$ Propofol dose: $mg.kg^{-1}$ End-tidal sevoflurane at device insertion; %	 1.4 (0.3) 3.2 (0.7) 4.8 (1.1)
Duration: min Anaesthesia Surgery Controlled ventilation	 27.2 (15.9) 22.7 (15.7) 21.8 (14.3)

Note: Values are reported as mean (SD), median (IQR [range]) or number (proportion).

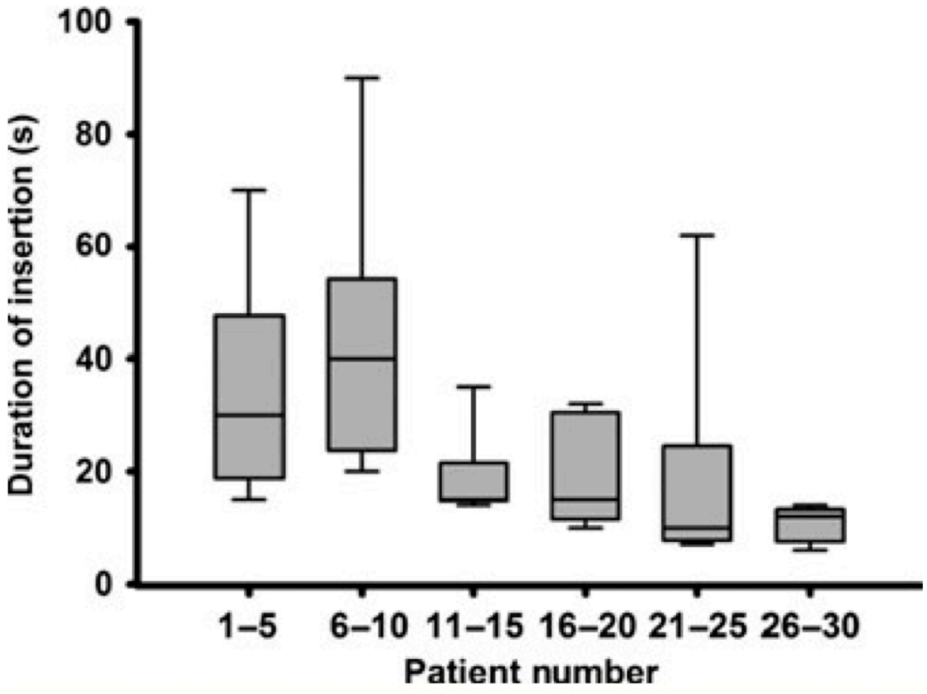

Figure 3.2. Graph demonstrating the decrease in the mean duration of insertion for successful attempts at Baska™ mask placement.

Note: The box-whiskers represent subsequent groups of five patients. Horizontal line – median; box – IQR; whiskers – range.

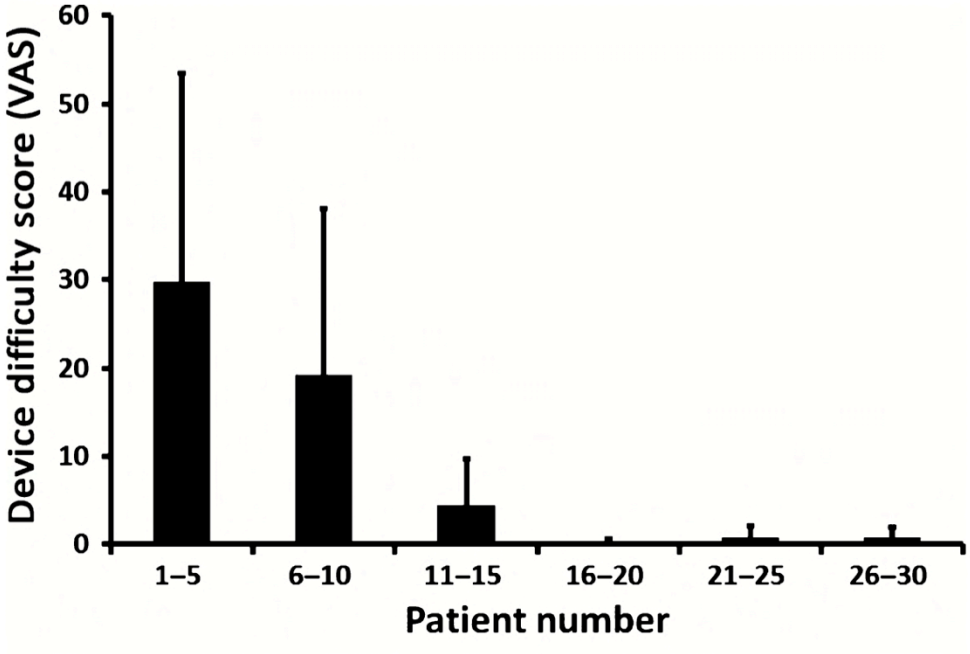

Figure 3.3. Graph demonstrating the decrease in the device difficulty scores with Baska™ mask use in consecutive patients.

Note: The histogram bars correspond to subsequent groups of five patients. The error bars indicate SD.

3.3.4. Baska™ Mask Performance Characteristics

3.3.4.1. Airway Seal

An audible leak was present immediately after device insertion in nine (30%) patients (Table 3.6). After 5 minutes the leak had disappeared in six (66.7%) of these patients. This suggests the cuff seal improves over time. It should be noted that seven of the nine patients with an audible leak at 0 minutes were in the first 10 patients recruited, thus operator inexperience might have been a contributing factor.

The mean (SD) leak pressure was 35.7 (13.3) cm H_2O. Again, there was evolution in the leak pressures as the operator got more familiar with the device, with the leak pressure 19.4 (7.5) cm H_2O in the first five patients, and 39 (9.2) cm H_2O in the last five patients (Figure 3.4). The leak test was interrupted once the airway pressure reached 50 cm H_2O, which occurred in 4 (13%) patients. In two patients the test was terminated prematurely due to the development of a reflex bradycardia.

3.3.4.2. Airway Stability

Evaluation of the mask stability utilising different head positions showed reassuring results. The leak fraction changed from a median of 5.4% in the neutral position to a maximum of 9.8% in head without pillow position (Table 3.6).

Table 3.6. Data regarding Baska™ mask performance and complications

Airway leak pressure; cm H_2O	35.7 (13.3)
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])
Patients with audible leak:	
at 0 min	9 (30%)
at 5 min	3 (10%)
Peripheral oxygen saturation during insertion attempt	
Lowest value; %	98 (3)
Patients with SpO_2 < 90%	1 (3%)
Patients with SpO_2 < 85%	0
Laryngospasm	0
Blood staining	7 (23%)
Lip damage	0
Teeth damage	0

Note: Values are reported as mean (SD), median (IQR [range]) or number (proportion).

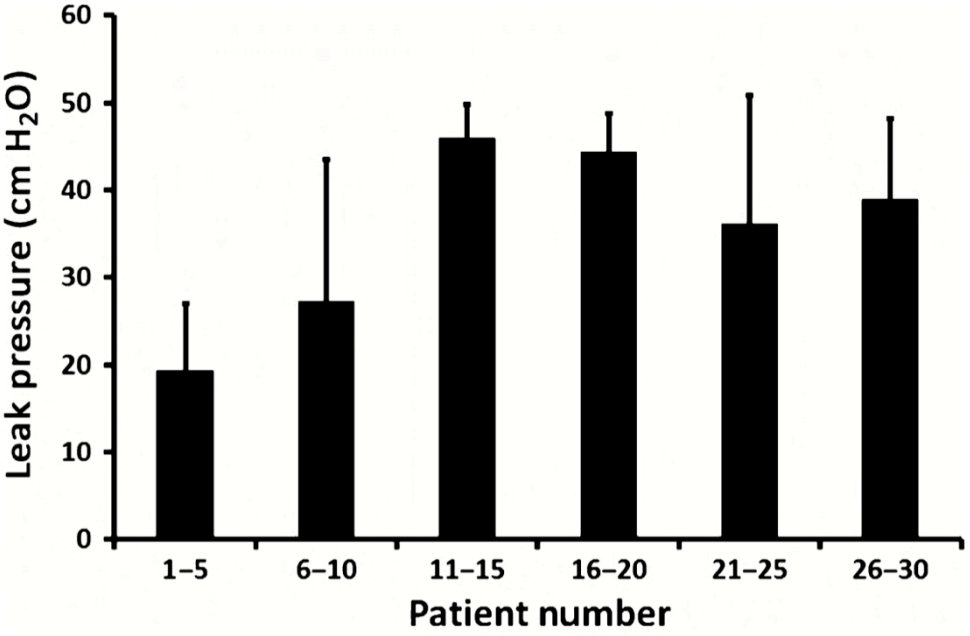

Figure 3.4. Graph demonstrating the increase in mean leak pressures with consecutive patients.

Note: The histogram bars correspond to subsequent groups of 5 patients. The error bars indicate SD.

3.3.5. Baska™ Mask Complications

The incidence of complications was low (Table 3.6). During mask placement only one patient experienced brief arterial oxygen desaturation under 90% (namely to 87%). This was likely due to prolonged manoeuvring of the Baska™ mask during placement in an obese patient with a BMI of 33 $kg.m^{-2}$. Minor blood staining was present on mask removal in seven patients (23%). There were no occurrences of laryngospasm, lip or dental injury.

3.3.6. Patient Comfort Indices

We assessed the patients for throat pain, dysphonia and dysphagia on arrival and discharge from the Recovery Room as well as on the following day. The results are presented in Table 3.7.

Table 3.7. Data regarding patient comfort indices

Severity of throat discomfort; VRS	
On arrival to 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; VRS	
On arrival to 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; VRS	
On arrival to PACU	0 (0-0 [0-2])
On discharge from PACU	0 (0-0 [0-1])
1st postoperative day	0 (0-0 [0-0])

Note: Values are reported as median (IQR [range])

3.4. Discussion

These data constituted the first published findings of a clinical evaluation of the Baska™ mask [106].

3.4.1. Baska™ Mask Insertion

We observed reasonable success rates (overall 97% and on first attempt 77%), especially given the fact that the operator was unfamiliar with the device. There were no previous clinical use data so extra caution was exercised during the insertion attempts. The insertion parameters (success rates, insertion times, leak pressures and device difficulty scores) improved over time as the operator progressed over the device learning curve. In our cohort there was a sustained improvement in the insertion parameters after the first 10 patients, suggesting the learning curve for the Baska™ mask may be short. Further studies are needed to examine this hypothesis [42, 107].

3.4.2. Device Difficulty Score

The operator rated VAS device difficulty score is subjective. In our case the device difficulty score evolved reflecting a learning effect (Figure 3.3). Apart from the genuine reflection of an increased skill in using the device this evolution may reflect the operator "enthusiasm" from mastering the device while in fact the device might be relatively difficult to use. Such scores are likely to be more useful in the setting of a randomised controlled trial comparing two or more devices inserted by operators skilled in their use.

3.4.3. Baska™ Mask Performance

The leak pressures we observed with the Baska™ mask compared well with the data published for other supraglottic airway devices (LMA Unique™, LMA ProSeal™, i-gel®) [51, 86-88]. This is indicative of a superior airway seal. Given the design of the leak test used and the learning effect observed our data likely underestimate the true leak pressure. Firstly the airway leak pressures improved in subsequent patients indicating a learning effect as demonstrated in Figure 3.4. Secondly, the leak test was limited to a maximum airway pressure of 50 cm H_2O, which occurred in 4 (13%) patients. Thirdly, in

two patients the test was terminated prematurely due to the development of a reflex bradycardia.

Our observations demonstrated some difficulties. The Baska™ mask cuff orifice is relatively small and sufficient alignment with the laryngeal inlet is necessary to ensure an adequate ventilation. This hypothesis is supported by the fact that in 12 (40%) patients optimisation manoeuvres were needed to effect a successful mask placement. The audible leak present immediately after mask placement in 9 (30%) patients disappeared after 5 minutes in 6 of them. A potential explanation is that the leak pressure test and the ensuing positive pressure ventilation facilitated the Baska mask cuff expansion and improved the airway seal.

3.4.4. Baska™ Mask Safety Profile

Apart from the relatively high incidence of minor blood staining on mask removal the safety data from our study are reassuring. The incidence of throat pain, dysphagia and dysphonia was low. These results are reassuring but the most appropriate way to evaluate patient comfort indices would be with a large randomised controlled trial.

The removable suction port connector was easily displaceable, representing a potential risk for an airway obstruction. This was communicated to the manufacturers and we were informed that the design has been changed and the connector secured.

3.4.5. Study Limitations

Our study was an observational study on a small cohort of patients. It was intended as a pilot study to accumulate initial safety and performance data. Our results should not be used as an argument for or against routine clinical use; the observed device insertion success, respectively failure rates must be interpreted with caution given the small sample size [105]. Initial experience in male patients suggested greater variability compared with females with regard to the sizing of the Baska™ mask, thus the study was restricted to female patients. Patient and investigator bias was possible, as the study was

not blinded. All devices were placed by one experienced anaesthetist. The operator had limited exposure to the Baska™ mask prior to this study. The results demonstrate learning effect thus are likely to underestimate the performance of the device in the hands of an operator well trained in its use. As we did not have access to prior clinical data (apart from limited personal advice from the device inventors) we exercised extra caution, which also may have affected our results. The proportion of time our patients were receiving controlled ventilation was high (Table 3.5) thus the performance of the Baska™ mask in spontaneously ventilating patients remains to be determined.

3.5. Conclusions

Our data suggests that the Baska™ mask demonstrates a level of utility as an alternative supraglottic airway that is worthy of further clinical study. This new device demonstrated the highest airway leak pressures in its class, indicative of a superior airway seal.

4. Comparison of the Baska™ Mask with the Laryngeal Mask Airway in Female Patients

4.1. Introduction

In our pilot observational study of the Baska™ mask in female patients [106] we found an overall insertion success rate of 96.7% (95% CI 83-100%) and an airway leak pressure 35.7 (13.3) cm H_2O. We wished to examine the clinical utility of this novel supraglottic airway device in a randomised controlled study comparing it with a single-use classic laryngeal mask airway (cLMA) (Integral Medical Products, Zhejiang, China) in low- risk female patients undergoing ambulatory surgery. We hypothesised that the Baska™ mask would have a better airway seal, as reflected by greater airway leak pressure as compared with the cLMA; and would have a first time insertion success rate that is not inferior to that seen with the cLMA.

The results of this study have been published in the following paper:
Alexiev, V., Ochana, A., Abdelrahman, D., Coyne, J., McDonnell, J.G., O'Toole, D.P., Neligan, P., Laffey, J.G., Comparison of the Baska™ mask with the single-use laryngeal mask airway in low-risk female patients undergoing ambulatory surgery. Anaesthesia. 2013 Oct; 68(10); p.1026-32

4.2. Methods

4.2.1. Patient Selection

This randomised controlled trial was approved by the Galway University Hospitals Research Ethics Committee (Ref. C.A. 724). Following written informed consent, 150 female patients of ASA physical status 1-3, 16-85 years of age, deemed to be at a low risk for difficult tracheal intubation were recruited. The inclusion and exclusion criteria are shown in Table 4.1.

Table 4.1. Study inclusion and exclusion criteria.

Inclusion Criteria	Exclusion Criteria
▪ ASA physical status 1-3 ▪ Age 16-85 ▪ BMI ≤ 35 $kg.m^{-2}$ ▪ Non-urgent surgery of planned duration < 4 hrs.	▪ Patients unwilling or unable to give consent ▪ Neck pathology ▪ Previous or anticipated problems with the upper airway or the upper gastrointestinal tract ▪ Live pregnancy ▪ Increased risk of gastric aspiration

4.2.2. General Anaesthesia

Standardised general anaesthetic was provided [101, 102]. Standard monitoring was utilised throughout, including ECG, non-invasive blood pressure, pulse oximetry and end-tidal gas monitoring [108]. Fentanyl or remifentanil (1-1.5 $\mu g.kg^{-1}$) was given intravenously. Sleep dose of propofol (2.0-4.0 $mg.kg^{-1}$) was titrated to induce anaesthesia. Manual ventilation was commenced with sevoflurane (2.0-4.5%) or desflurane (4.0-6.5%) in oxygen. Additional increments of propofol were given if needed to produce a sufficient jaw relaxation to facilitate the supraglottic airway device insertion. In this study the additional propofol doses were recorded separately from the initial dose used to induce anaesthesia.

4.2.3. Device Insertion

All device insertions were performed by one of four investigators (V. Alexiev, A. Ochana, J. McDonnell and J. Coyne). All received training in the placement of the Baska mask and performed more than 30 insertions, and have performed over 100 prior insertions of the cLMA. Up to three insertion attempts of the allocated device were permitted per patient. During the first attempt the Baska™ mask and the cLMA size choice was based on the patient's ideal body weight [109-111] and the manufacturer's instructions, as shown in Table 3.2.

If the device did not function properly, the following manipulations were performed in sequence: the device was pushed further in, rotated and withdrawn slightly. If an effective airway was not achieved, the device was removed. If the problem was deemed to be due to a large leak, a device one size bigger was used during the following attempt. If the device was deemed too large, as evidenced by difficulty in advancing it into the pharynx and in ventilating the patient, a device one size smaller was inserted. Following 3 failed insertion attempts, the alternative supraglottic airway device was inserted. If this failed the back-up plan was tracheal intubation.

4.2.4. Maintenance of Anaesthesia

Once the airway was secured with the respective device, mechanical ventilation was maintained until spontaneous ventilation supervened. Anaesthesia was provided with sevoflurane or desflurane in a mixture of oxygen and air or N_2O. Where a cLMA was used the cuff pressure was checked using a hand-held pressure gauge (Tyco Healthcare, Hampshire, UK), and adjusted, if needed, to keep the cuff pressure below 60 cm H_2O [112]. Further management was left to the discretion of the primary anaesthetist.

4.2.5. Data Collection

An unblinded independent observer collected all mask insertion-related data. "Duration of device insertion attempt" was defined as the time from the moment the device was touched by the operator until successful ventilation (defined as bilateral chest expansion and an end-tidal CO_2 with plateau) was achieved or the device was removed [103, 104]. "Successful placement" was defined as the presence of bilateral chest expansion, a satisfactory end-tidal carbon dioxide tracing with a plateau and an estimated leak fraction of less than a third of the inspired tidal volume [52, 87]. The insertion data collected are listed in Table 3.3. In this study we used the term "successful ventilation" separately from the term "successful placement". The former allowed for more precise recording of the device insertion duration while the latter allowed for more rigid definition of good device performance.

4.2.6. Mask Leak Test

A leak test was performed as described in Section 3.2.6. In patients in whom the airway pressure reached 40 cm H_2O the leak test was immediately interrupted as a safety precaution and a value of 40 cm H_2O was recorded.

The stability of the placement of the mask was assessed by determining the leak fraction as described in Section 3.2.6.

4.2.7. Data Regarding Complications

The following complications were specifically monitored: arterial oxygen desaturation; lip damage; blood staining on mask removal; and laryngospasm [103, 104]. We evaluated the incidence and severity of throat pain, dysphonia, dysphagia and heartburn in the recovery room (on arrival and discharge), as well as on the first and third postoperative day using a 10-point verbal rating scale (VRS). In this study we also followed up with the patients regarding the incidence and severity of nausea and vomiting on the day of surgery and on the first postoperative day.

4.2.8. Sample Size and Statistical Methods

We performed two separate sample size calculations, one for each of our hypotheses. To test our first hypothesis, we considered that an airway leak (seal) pressure of the Baska™ mask of 20% greater than that of the cLMA would be a clinically important difference. The cLMA leak pressures reported in previous studies were ≈ 20 cm H_2O, with SD 10 cm H_2O [51, 86-88]. With type-1 error of 0.05 and a power of 80% we calculated that the sample size required would be 50 in each group, or 100 in total, based on a parallel group study design. Regarding our second hypothesis (of non-inferiority of the Baska mask re first insertion attempt success rate) we defined “inferior” for the purpose of this study a success rate of 15% lower than that observed with the cLMA. The first time insertion success rate reported for the cLMA is as high as 97% [113]. With a type-1 error of 0.05 and a power of 80% we calculated that a sample size of 121 would be required in each group, or 242 in total, based on a parallel group study design. With this two sample size calculations and in order to minimise the potential for data loss, we planned

to enrol 125 patients in each group, or 250 in total. We planned an interim analysis once 150 patients were recruited, with the aim of terminating the study if at that point the second primary hypothesis was disproven with a p-value < 0.01. Patients were randomised using batches of sealed envelopes, separately for each operator placing the devices.

The data for continuous variables (leak pressure, insertion duration etc.) were analysed using a *t*-test or a rank-sum test depending on the data distribution. The data were analysed on an intention-to-treat basis. The categorical data were analysed with a rank-sum test or a chi-squared test as appropriate. The α level for all analyses was set at $p < 0.05$. All tests were performed with Sigmastat™ statistical software (Systat Software Inc, California, USA).

4.3. Results

After 150 patients were recruited an interim analysis was performed and the study was terminated as the stopping criteria were fulfilled (Figure 4.1).

4.3.1. Patient Demographics

The patient characteristics were comparable between both groups (Table 4.2). The Baska™ mask group consisted of 71 patients of age 23 to 75 years and the cLMA group included 79 patients of age 17 to 83 years. None of the patients had a history of previous difficulties with airway management and despite the slightly higher Mallampati scores in the cLMA group all participants were deemed to have favourable airways.

The majority of the patients in both groups underwent minor non-laparoscopic gynaecological (e.g. hysteroscopy, curettage, cystoscopy, ERPC) or breast surgery procedures. Gynaecological laparoscopic procedures were performed in 30% of the patients in the Baska™ group, and in 20% in the cLMA group. In the majority of patients in both groups, the anaesthetic time did not exceed 1 hour. Eight patients (11%) in the Baska™ mask group and 11 patients (14%) in the cLMA group had longer anaesthetic time (62-183 minutes, respectively 64-142 minutes). On average, the patients underwent controlled ventilation for over 90% of the total anaesthetic time in both groups.

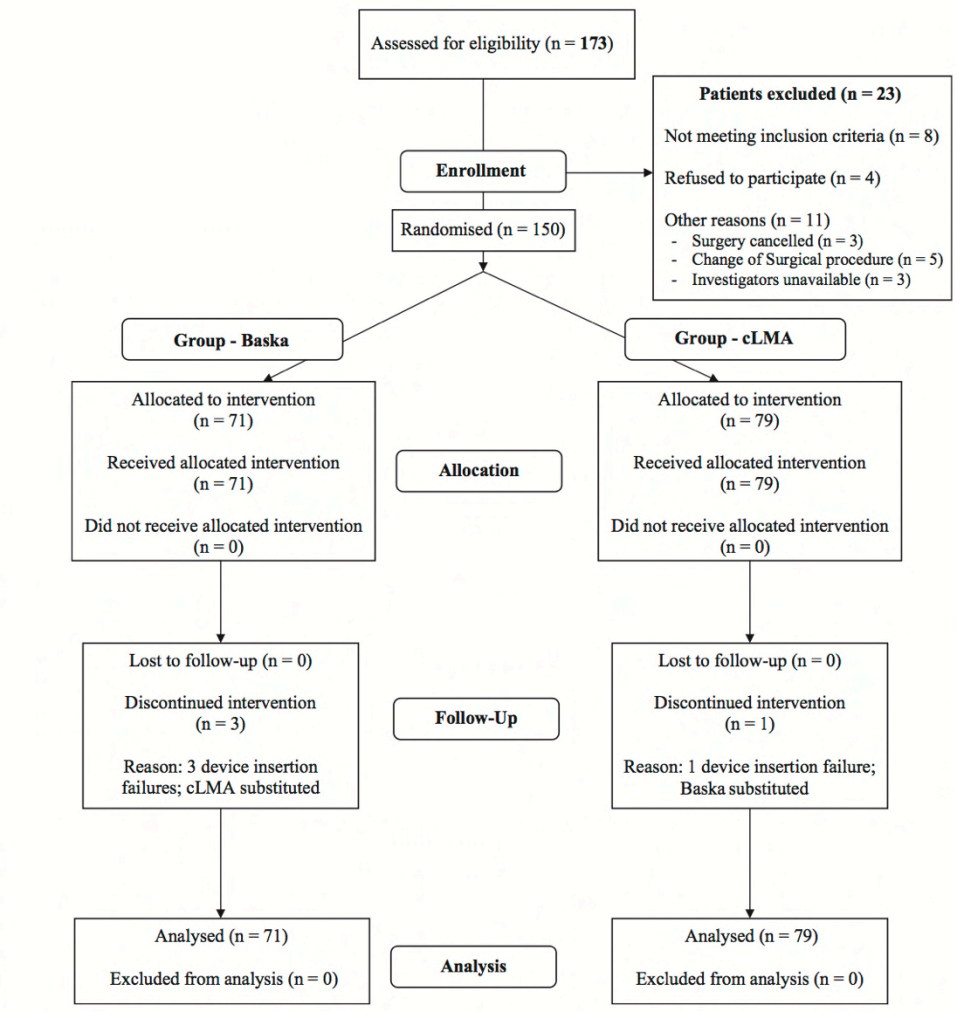

Figure 4.1. Patient recruitment flowchart

Table 4.2. Characteristics of the patients enrolled in the study

	Baska™	cLMA	p-values
Number of patients	71	79	
Age; years	46.9 (12.7)	45.1 (13.7)	0.356
Body mass index; $kg.m^{-2}$	26.0 (4.5)	25.7 (4.0)	0.404
Patient height; cm	165.5 (6.9)	164.6 (6.8)	
Patient weight; kg	71.1 (13.1)	69.5 (10.6)	
ASA physical status	1 (1-2 [1-3])	1 (1-2 [1-3])	0.179
Airway measurements			
Thyromental distance; cm	7.9 (1.4)	8.2 (1.4)	0.202
Inter-incisor distance; cm	4.7 (1)	4.6 (1)	0.392
Mallampati classification	1 (1-2 [1-2])	1 (1-2 [1-3])	0.093
1	49 (69%)	44 (56%)	
2	22 (31%)	31 (39%)	
3	0	4 (5%)	
4	0	0	
Type of surgery			
Gynaecologic non-laparoscopic	29 (41%)	35 (44%)	
Gynaecologic laparoscopic	21 (30%)	16 (20%)	
Breast	19 (27%)	23 (29%)	
Other	2 (3%)	5 (6%)	

Note: Values are reported as mean (SD), median (IQR [range]) or number (proportion).

4.3.2. Baska™ Mask Insertion

Anaesthetic management and device insertion data are summarised in Table 4.3.

Our hypothesis of non-inferiority of the first time insertion success rates was disproved, as the success rate for the Baska™ mask was significantly lower (73%) as compared to the cLMA (98%), $p < 0.001$ (Figure 4.2). It should be noted that the overall success rates were not significantly different (96% versus 99%, p 0.54, Table 4.3).

Comparison of the operator-rated VAS device difficulty scores indicated that the Baska™ mask was more difficult to insert (Figure 4.3) as compared to the cLMA. This finding is in line with the significantly longer duration of the successful insertion attempts (Figure 4.4), higher number of insertion attempts (Figure 4.2) and higher number of additional optimisation manoeuvres (65% vs 4%, $p < 0.001$) (Table 4.3) in the Baska™ mask group.

More patients required additional increments of propofol during mask insertion in the Baska™ versus the cLMA group (38% vs. 14%, $p < 0.001$), with significantly higher total propofol dose (Table 4.3). This may be related to the longer insertion times in the Baska™ group (Figure 4.4). The haemodynamic parameters were comparable between the groups pre- and post-device insertion (Table 4.4).

Table 4.3. Anaesthesia management and device insertion data

	Baska™ (n = 71)	cLMA (n = 79)	p values
First-time insertion success rate	52 (73%)	77 (98%)	< 0.001
Overall insertion success rate	68 (96%)	78 (99%)	0.54
Number of insertion attempts	1 (1-2 [1-3])	1 (1-1 [1-3])	0.012
1	52 (73%)	77 (98%)	
2	15 (21%)	1 (1%)	
3	4 (6%)	1 (1%)	
Number of additional manoeuvres	1 (0-2 [0-3])	0 (0-0 [0-3])	< 0.001
0	25 (35%)	76 (96%)	
1	28 (39%)	2 (2.5%)	
2	9 (13%)	0	
3	9 (13%)	1 (1.5%)	
Induction of anaesthesia			
Fentanyl dose: $\mu g.kg^{-1}$	1.4 (0.3)	1.4 (0.2)	0.333
Induction propofol dose: $mg.kg^{-1}$	2.8 (0.5)	2.8 (0.5)	
Patients given additional propofol boluses	27 (38%)	11 (14%)	0.001
Total propofol dose: $mg.kg^{-1}$	3.3 (0.8)	3.0 (0.7)	0.006
End-tidal volatile; MAC equivalents	2.2 (0.9)	1.9 (0.7)	0.056
Duration of procedure; min			
Anaesthesia	40.8 (29.3)	41 (26.3)	0.901
Surgery	34 (25.8)	34.8 (24.8)	0.807
Controlled ventilation	38.1 (26.8)	37 (26)	0.848

Note: Values are reported as mean (SD), median (IQR [range]) or number (proportion).

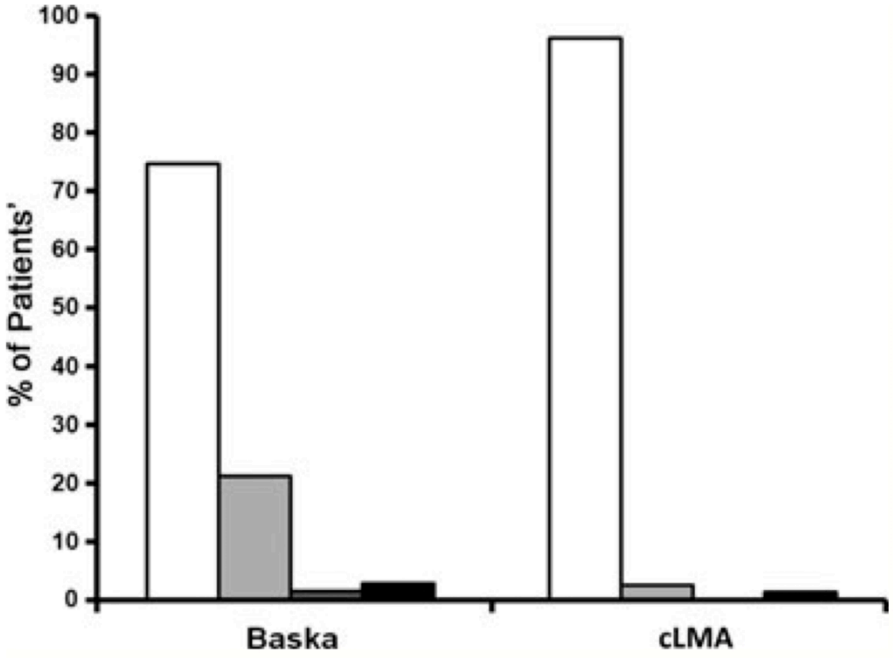

Figure 4.2. Graph depicting device insertion success rates

Note: The columns represent the proportion of patients that required 1 insertion attempt (□), 2 insertion attempts (■), 3 insertion attempts (■) and who did not have a successful mask placement (■) with the Baska™ mask and the cLMA. The first time insertion success rate was significantly greater ($p < 0.001$) with the cLMA as compared with the Baska™ mask, but the overall success rates were similar with both masks (p 0.54).

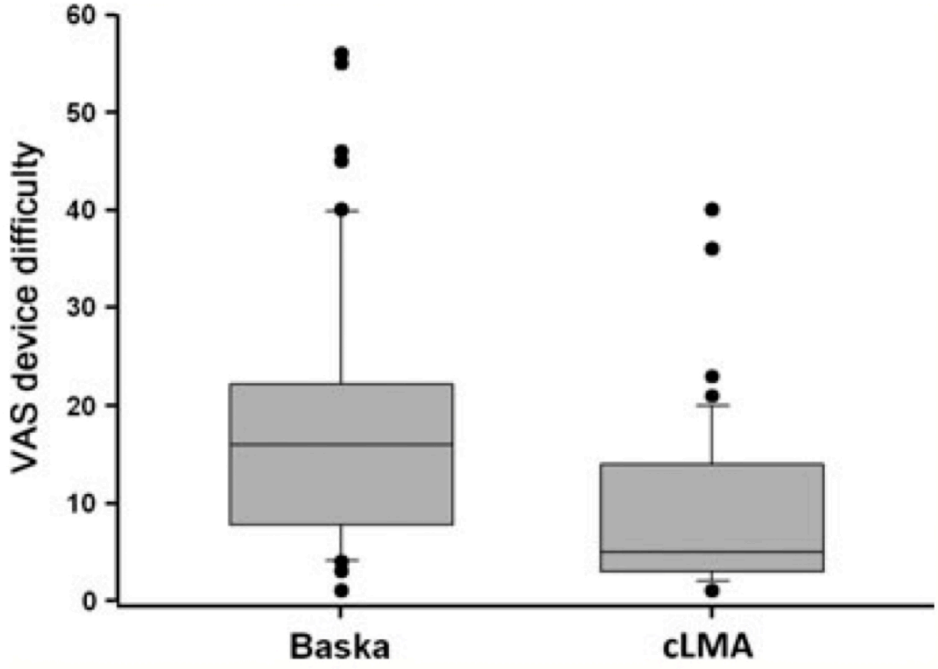

Figure 4.3. Graph representing user-rated device difficulty scores for the Baska™ mask and the cLMA.

Note: The bottom and top of the box represent the first and third quartiles, the band inside the box represents the median value, the whiskers represent the 10th and the 90th percentile, and the black dots represent outliers. $p < 0.001$. The investigators rated the device difficulty score using a 100 mm visual analogue scale.

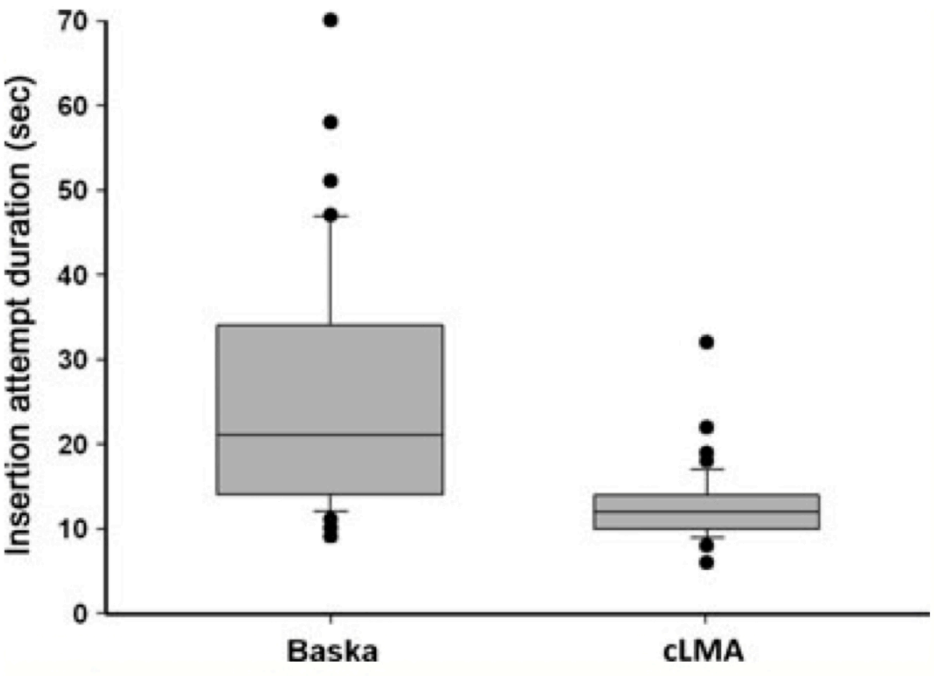

Figure 4.4. Graph depicting the duration of successful insertion attempts for the Baska™ mask and the cLMA

Note: The bottom and top of the box represent the first and third quartiles, the band inside the box represents the median value, the whiskers represent the 10th and the 90th percentile, and the black dots represent outliers. $p < 0.001$.

4.3.3. Baska™ Mask Performance Characteristics

The device performance and safety data are shown in Table 4.4. The study results confirmed our first hypothesis that the airway leak pressure of the Baska™ mask would be significantly higher than that of the cLMA (Table 4.4, Figure 4.5). Airway obstruction due to misalignment or size discrepancy between the device cuff orifice and the glottic opening were not contributing to the high leak pressures of the Baska™ mask as the peak airway pressures and inspiratory volumes were comparable between the groups (Table 4.4). Our results indicate that the Baska™ mask has superior airway seal compared to the cLMA.

An audible leak was present in 18 patients (25%) immediately after Baska™ mask placement. It disappeared within 5 minutes in all but one patient, suggesting the airway seal improved over time. Interestingly, we had similar findings in the LMA group.

Intraoperative device repositioning was required in 2 patients (3%) in the Baska™ mask group and in 1 patient (1%) in the LMA group. This difference did not reach statistical significance yet our study was not aimed at detecting such.

4.3.4. Baska™ Mask Complications

The incidence of minor blood staining on mask removal was higher in the Baska™ mask group (Table 4.4) yet both groups were comparable in terms of patient comfort indices (Table 4.5). The incidence of laryngospasm was similar in both groups (Table 4.4).

There were no instances of lip or teeth damage recorded in this study.

Table 4.4. Data regarding device performance and complications.

	Baska™ (n = 71)	cLMA (n = 79)	P values
Airway leak pressure; cm H_2O	36.5 (5.9)	22.1 (5.5)	< 0.001
Ventilatory variables			
Peak airway pressure; cm H_2O	15.9 (4.1)	14.7 (3.2)	0.04
Inspiratory volume; ml	448 (31)	454 (38)	0.27
Leak volume; ml	19 (17)	16 (13)	0.25
Size of mask placed successfully:			
3	0	6 (8%)	
4	34 (50%)	70 (89%)	
5	34 (50%)	2 (3%)	
Peripheral oxygen saturations during			
insertion attempt; %	99.1 (0.8)	99.0 (0.7)	0.634
Lowest value	0	0	
Patients with SpO_2 < 95%			
Haemodynamic data pre-insertion			
Heart rate; bpm	71 (14.4)	72.8 (12.8)	0.26
Mean BP; mm Hg	72 (15.7)	67.4 (14.4)	0.096
Haemodynamic data post-insertion			
Heart rate; bpm	68 (13.3)	69.8 (12.9)	0.145
Mean BP; mm Hg	71 (16.5)	66.7 (15.9)	0.238
Need to reposition mask intraop.	2 (3%)	1 (1%)	0.52
Laryngospasm on emergence	1 (1%)	3 (4%)	0.79
Blood staining on mask at removal	13 (18%)	5 (6%)	0.045

Note: Values are reported as mean (SD), median (IQR [range]) or number (proportion).

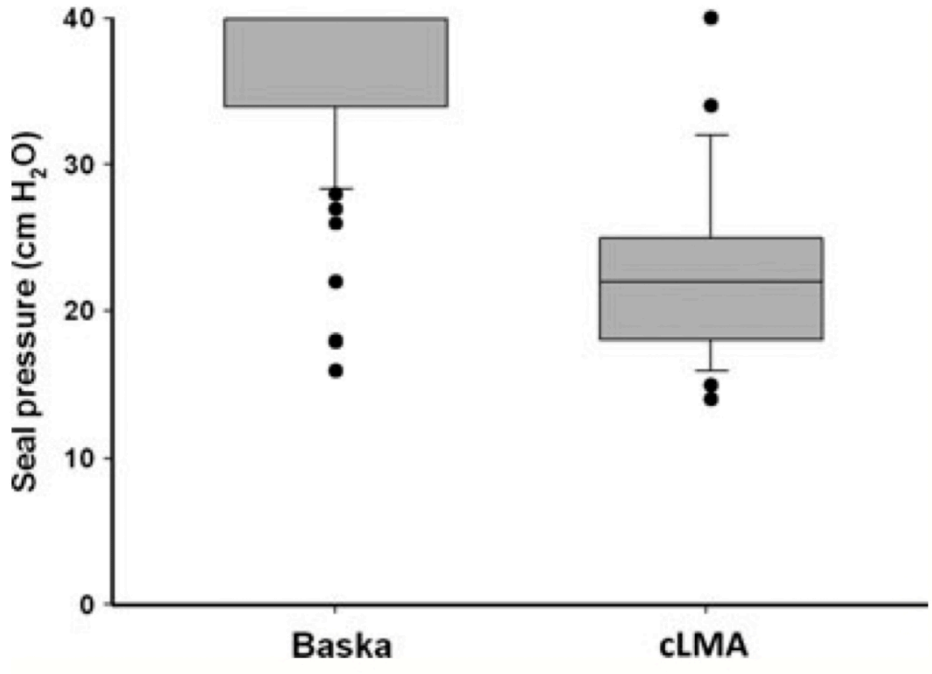

Figure 4.5. Graph depicting seal pressures achieved with the Baska™ mask and the cLMA.

Note: The bottom and top of the box represent the first and third quartiles, the band inside the box represents the median value, the whiskers represent the 10th and the 90th percentile, and the black dots represent outliers. For the Baska™ mask the median and the 3rd quartile are superimposed. $p < 0.001$

Table 4.5. Patient comfort data

	Baska™ (n = 71)	cLMA (n = 79)
Severity of throat pain; VRS		
On arrival to PACU	0 (0-1 [0-5])	0 (0-0 [0-6])
On discharge from PACU	0 (0-1 [0-9])	0 (0-0 [0-5])
1st postoperative day	0 (0-2 [0-5])	0 (0-0 [0-6])
3rd postoperative day	0 (0-0 [0-6])	0 (0-0 [0-7])
Severity of dysphagia; VRS		
On arrival to PACU	0 (0-3 [0-6])	0 (0-0 [0-6])
On discharge from PACU	0 (0-1 [0-5])	0 (0-0 [0-4])
1st postoperative day	0 (0-1 [0-7])	0 (0-0 [0-5])
3rd postoperative day	0 (0-0 [0-4])	0 (0-0 [0-7])
Severity of dysphonia; VRS		
On arrival to PACU	0 (0-0 [0-3])	0 (0-0 [0-6])
On discharge from PACU	0 (0-0 [0-6])	0 (0-0 [0-8])
1st postoperative day	0 (0-0 [0-5])	0 (0-0 [0-5])
3rd postoperative day	0 (0-0 [0-4])	0 (0-0 [0-6])
Severity of heartburn; VRS		
On arrival to PACU	0 (0-0 [0-0])	0 (0-0 [0-1])
On discharge from PACU	0 (0-0 [0-0])	0 (0-0 [0-2])
1st postoperative day	0 (0-0 [0-2])	0 (0-0 [0-10])
3rd postoperative day	0 (0-0 [0-3])	0 (0-0 [0-6])
Severity of nausea		
On the day of surgery	0 (0-0 [0-10])	0 (0-2.5 [0-9])
1st postoperative day	0 (0-0 [0-7])	0 (0-0 [0-9])
Severity of vomiting		
On the day of surgery	0 (0-0 [0-9])	0 (0-0 [0-8])
1st postoperative day	0 (0-0 [0-8])	0 (0-0 [0-9])

Note: Values are reported as median (IQR [range])

4.4. Discussion

In our study of low risk female patients undergoing ambulatory surgery we found that the Baska™ mask provides a better airway seal as compared to the cLMA. Yet our results indicate the Baska™ mask is more difficult to use, with lower first-time insertion success rates, longer insertion times and higher user-rated device difficulty scores.

4.4.1. Baska™ Mask Insertion and Device Size

The insertion success rates for the Baska™ mask in our previous observational study of 30 patients [106] compare well with the results of this randomised controlled trial. As might be expected the quality of the estimates is improved with the bigger sample size. This is reflected by lesser spread in the respective confidence intervals [114]. The first time Baska™ mask insertion rate in the observational study was 77% (95 CI 58-90%) as compared with 73% (95% CI 61-83%) in the randomised controlled trial. The overall success rate was 97% (95% CI 83-100%) in the observational study versus 96% (95% CI 88-99%) in the randomised controlled trial.

The lower first-time insertion success rate in the Baska™ group may be related to the mask sizing guidelines we used in our trials. We followed the manufacturer-recommended approach based on patients' weight. In most of the patients in whom the first insertion attempt failed we successfully placed a Baska™ mask of a different – usually larger - size. In the group of patients where Baska™ mask was placed successfully size 4 was used in 50% and size 5 was used in 50% of them.

Previously we described the need for sufficient alignment of the relatively small Baska™ mask cuff orifice against the glottic opening to effect optimal ventilation [106]. This is supported by the fact that higher number of optimisation manoeuvres was required in the Baska™ mask group as compared to the cLMA group in our randomised controlled trial (Table 4.3).

The device difficulty scores we recorded in our initial observational study [106] have different significance as compared to the scores in this clinical trial. The former scores illustrate an operator learning effect (Figure 3.3); the latter scores allow for comparison of two devices used by the same operators (Figure 4.3).

4.4.2. Baska™ Mask Performance

The airway leak pressures for the Baska™ group are likely to underestimate the true values, as the test we used was restricted to 40 cm H_2O. We reached this value in 43 patients (61%). Furthermore in our prior observational study we used less conservative cut-off of 50 cm H_2O and in 4 (13 %) of these patients a value of 50 cm H_2O was recorded (Figure 3.4).

The Baska™ mask cuff expansion due to the positive pressure generated by the airway leak test and the subsequent positive pressure ventilation may improve the airway seal. This assumption is supported by the fact that the audible leak present in 18 patients (25%) immediately after mask placement disappeared within 5 minutes in all but one patient. This finding is in line with the results from our observational study [106]. The audible leak present at insertion in 12 patients (15%) in the cLMA group disappeared in all but 2 patients after 5 minutes indicating that the seal may evolve with the LMA as well.

4.4.3. Baska™ Mask Complications

The incidence of blood staining on device removal was higher in the Baska™ mask group. Despite of that the patient comfort indices were comparable between both groups up to 3 days after surgery. While our findings seem reassuring our study was not powered to detect a difference in the patient comfort indices.

4.4.4. Study Limitations

The results of our study have to be interpreted with caution. In our observational study on 30 patients with one operator we observed relatively short device use learning curve [106]. In this randomised controlled trial all 4 operators received training and performed at least 30 Baska™ mask placements before the study. Nevertheless they had more experience with the use of cLMA. This might have affected the insertion success rates.

The study was restricted to adult females and patients with expected difficult airway were excluded. The study was single-blinded thus investigator bias was possible, especially in respect of the operator rated device use difficulty scores. The study was terminated at the planned interim analysis stage as we demonstrated clearly that the airway leak pressures were higher and first-time success rates lower in the Baska™ mask group. The proportion of time our patients were receiving controlled ventilation was high (Table 4.3) thus the performance of the Baska™ mask in spontaneously ventilating patients remains to be determined.

4.5. Conclusions

The Baska™ mask provides superior airway seal in adult female patients with normal airways and is more difficult to insert as compared to the cLMA. The overall success rates were similar in both groups. The clinical significance of the superior airway seal remains to be determined but might be advantageous in certain scenarios (e.g. laparoscopic surgery etc.). Refinement of the sizing guidelines might improve the first-time insertions success rates.

5. Evaluation of the Success Rates and Device Sizing of the Baska™ Mask in Male Patients – a Pilot Study

5.1. Introduction

The Baska™ mask is a novel supraglottic airway device we previously evaluated on female patients in an initial observational study [106] and in a randomised controlled trial [53]. Optimal sizing of any supraglottic airway device may be problematic [88] but a guide is required for future evaluation and clinical use. Previous studies have looked into the best way to predict the correct sizing of other supraglottic devices, such as the laryngeal mask airway [109, 115]. While the optimal criteria remain elusive, weight and gender based approaches are being applied in the clinical practice [70, 116]. However, the reported experience with other supraglottic airway devices suggests that the initial manufacturer guidelines regarding device sizing might need revision [88].

We wished to evaluate the manufacturer recommended sizing criteria for the Baska™ mask [32] in male patients, and, in addition, to determine whether any criteria among a range of anthropometric patient characteristics may best predict successful Baska™ mask size selection. We also wished to continue to accumulate information regarding the performance and safety of this novel airway device.

The results of this study have been published in the following abstract: Alexiev, V., Ochana, A., Quinn, A., Foto, T., McDonnell, J.G., Laffey, J.G., Selection of optimum Baska™ mask size in male patients, an initial study. Irish J Med Sci. 2014; 183(Sup.1); p. S50

5.2. Methods

5.2.1. Patient Selection

This was a prospective single cohort study. Following Galway University Hospitals Ethics Committee approval (Ref. C.A. 653) and written informed consent, 28 male patients were recruited. The inclusion and exclusion criteria are shown in Table 5.1.

Table 5.1. Study inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
▪ ASA physical status 1-3 ▪ Age 16-85 ▪ BMI ≤ 35 $kg.m^{-2}$ ▪ Non-urgent surgery of planned duration < 4 hrs.	▪ Patients unwilling or unable to give consent ▪ Neck pathology ▪ Previous or anticipated problems with the upper airway or the upper gastrointestinal tract ▪ Expected difficult airway ▪ Increased risk of gastric aspiration

5.2.2. General Anaesthesia

Standard monitoring including ECG, non-invasive blood pressure, pulse oximetry and end-tidal gas monitoring, was used. Prior to induction, fentanyl 1-1.5 $\mu g.kg^{-1}$ was administered intravenously. Standardised induction of general anaesthesia was performed with propofol 2-4 $mg.kg^{-1}$. The patients were manually ventilated with a mixture of oxygen and sevoflurane (end-tidal concentration > 2%). Additional increments of propofol were given if needed to ensure sufficient jaw relaxation to facilitate device insertion.

5.2.3. Baska™ Mask Insertion

All device insertions were performed by one of two investigators (VA and AO) who received training and had performed over 30 insertions of Baska™ mask in female patients. Up to three insertion attempts were allowed per patient. The size of the mask used for the first placement attempt was determined in accordance with the manufacturer's guidelines based on the patient's weight

[32] (Table 3.2). If the device did not function properly the following manipulations were performed in sequence: the device was pushed further in, rotated and withdrawn slightly. If an effective airway was not achieved, the device was removed. If the problem was deemed to be due to a large leak, a device one size bigger was used during the following attempt. If the device was deemed too large, as evidenced by difficulty in advancing it into the pharynx and in ventilating the patient, a device one size smaller was inserted. Following 3 failed Baska™ mask insertion attempts, a LMA device was inserted.

5.2.4. Maintenance of Anaesthesia

Controlled ventilation was commenced using the following settings: inspiratory volume 6-10 $ml.kg^{-1}$, respiratory rate 9-12 breaths per minute and PEEP 0 cm H_2O. Peak and plateau airway pressures were recorded. Mechanical ventilation was maintained until spontaneous ventilation supervened. Anaesthesia was provided with sevoflurane in a mixture of oxygen and air or N_2O. Further management was left to the discretion of the primary anaesthetist.

5.2.5. Data Collection

Device insertion-related data were collected by an unblinded observer. "Duration of insertion attempt" was defined as the time from the moment the operator touched the device until adequate ventilation was achieved or the device was removed. "Adequate ventilation" was defined as the presence of a bilateral chest expansion and an $EtCO_2$ tracing with a demonstrable plateau phase.

As this study was aimed at examining the Baska™ mask sizing guidelines we expanded the set of criteria for device success with specific requirement for minimal acceptable airway leak pressure. "Successful placement" was defined as an ability to manually ventilate the patient, presence of a capnogram tracing with plateau, an estimated leak less than one third of the inspired volume on controlled ventilation, and an airway leak pressure greater than 15 cm H_2O.

The insertion data collected are listed in Table 3.3.

5.2.6. Mask Leak Test

A leak test was performed as described in section 3.2.6. In patients in whom the airway pressure reached 50 cm H_2O the leak test was immediately interrupted as a safety precaution and a value of 50 cm H_2O was recorded.

The stability of the placement of the Baska™ mask was assessed by determining the leak fraction as described in section 3.2.6.

5.2.7. Data Regarding Complications

Complications (arterial oxygen desaturation, lip or teeth damage, blood staining on mask removal, laryngospasm) were recorded.

Patients were followed on arrival and discharge from the post-anaesthesia care unit and on the first and third postoperative day (by ward visit or by telephone). The incidence of throat pain, dysphonia and dysphagia was recorded using a 10 – point verbal rating score (VRS).

5.2.8. Sample Size and Data Analysis

We planned to enrol a minimum of 20 and a maximum of 50 patients. Once 20 patients were enrolled a stopping rule (five consecutive successful placements on 1st attempt) was used to end recruitment (Figure 5.1).

We used descriptive statistics to summarise our data. Correlations between the successful Baska mask size and various anthropometric parameters were evaluated by visual inspection of scatter plots and box-whisker plots.

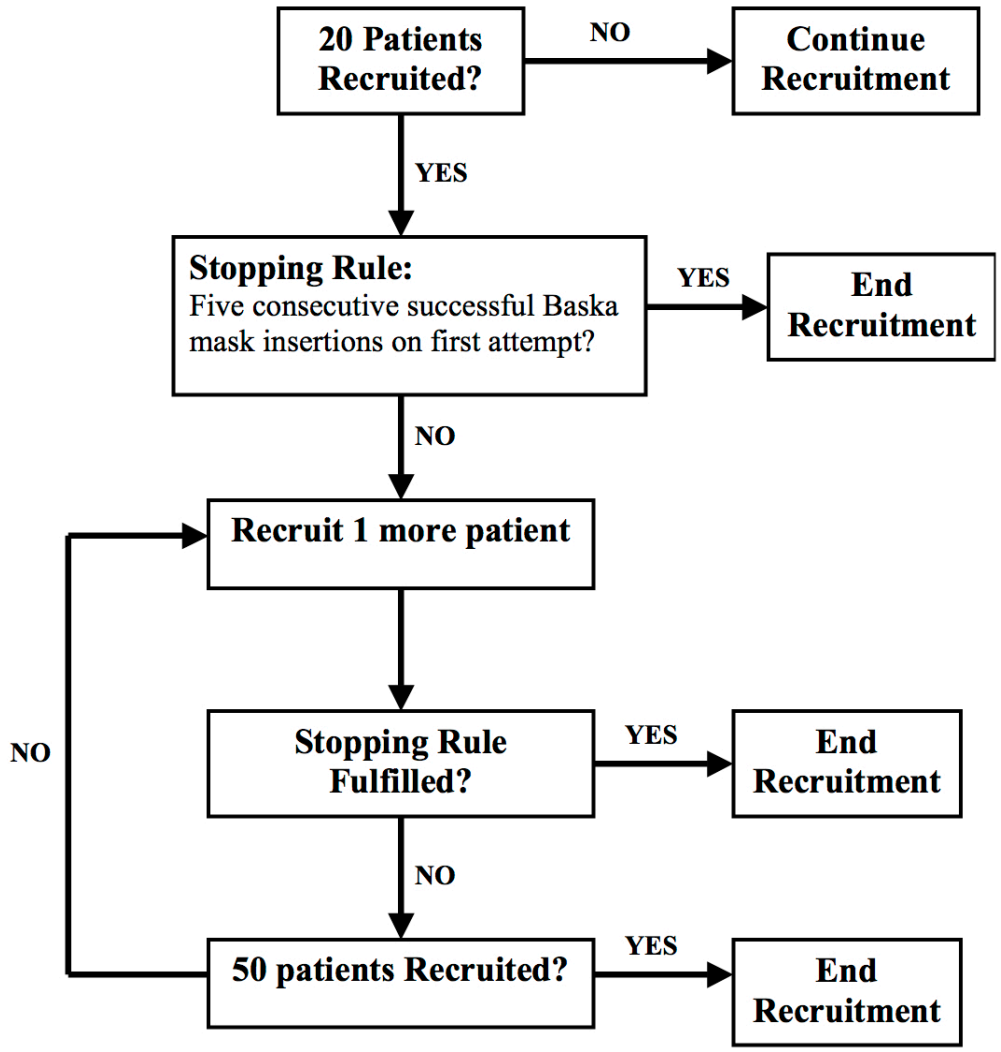

Figure 5.1. Patient recruitment flowchart

5.3. Results

The study was stopped after the recruitment of 28 patients as the stopping criteria were fulfilled.

5.3.1. Patient Demographics

The patient characteristics are presented in Table 5.2. Data regarding anaesthesia are presented in Table 5.3.

Our cohort consisted of 28 low risk adult male patients aged 17 to 85 years. The history and airway assessment were not suggestive of difficult intubation and all patients were deemed to have favourable airways. No patient had a BMI over 35 $kg.m^{-2}$.

Seventeen (61%) of our patients underwent minor urological procedures, 8 (28%) general surgical procedures (e.g. hernia repair or pilonidal sinus surgery) and the reminder other minor procedures. The anaesthetic time was between 15 and 125 minutes. On average the patients underwent controlled ventilation for 70% of the total anaesthetic time.

Table 5.2. Characteristics of the patients enrolled in the study

Number of Patients	28
Age (years)	54 (18.9)
Weight (kg)	85.9 (12.9)
Height (cm)	176.9 (6.6)
Body Mass Index ($kg.m^{-2}$)	27.4 (3.8)
ASA Classification:	2 (2-2 [1-3])
Airway Measurements	
Thyromental distance (cm)	7.7 (1.1)
Inter-incisor distance (cm)	5.1 (1.1)
Mallampati Classification	1 (1-2 [1-3])
1	18 (64%)
2	7 (25%)
3	3 (11%)
4	0 (0)
Type of Surgery	
Urology	17 (61%)
General surgery	8 (28%)
Orthopaedics	2 (7%)
Plastics	1 (4%)

Note: Data are reported as mean (SD), median (interquartile range, {range]) or as number (percentage).

5.3.2. Baska™ Mask Insertion

The data regarding insertion of the Baska™ mask are presented in Table 5.3.

The overall insertion success rate was 93%. In 20 of the 28 patients (71%) the Baska™ mask was successfully inserted on first attempt. Six patients required a second insertion attempt, while in two patients insertion of the Baska™ mask was unsuccessful, despite 3 insertion attempts.

Extra manoeuvres to optimise mask position during placement were utilised in 16 patients (57%). Additional propofol boluses during placement were required in 8 patients (29%).

5.3.3. Baska™ Mask Size

The size 5 Baska™ mask was used successfully in 53.6% patients, size 6 in 35.7% and size 4 in one patient (3.6%). Table 5.4 presents airway-related anatomical data, grouped according to the size of the Baska™ mask used successfully. The correlations between the successful mask size and various anthropometric indices are depicted in Figures 5.2 to 5.5.

The majority of patients in whom a size 5 Baska™ mask was used had weight under 90 kg and a height under 180 cm. In the size 6 group almost half of the patients had a weight under 90 kg and a height under 180 cm.

Table 5.3. Data regarding Baska™ mask insertion and anaesthetic management

Overall insertion success rate	26/28 (93%)
Number of insertion attempts 1 attempt 2 attempts 3 attempts (both failed)	1 (1,2 [1,3]) 20 (71.4%) 6 (21.4%) 2 (7%)
Requirement for optimisation manoeuvres	16 (57%)
Extra boluses of propofol to facilitate insertion	9 in 8 pts (29%)
Duration of insertion attempts; s First insertion attempt Successful insertion attempt	 29 (22) 26 (15))
Device difficulty score; VAS 0-100 mm	21.1 (15.6)
Size of Baska™ mask inserted 4 5 6	 1 (3.6%) 15 (53.6%) 10 (35.7%)
Induction of anaesthesia Fentanyl dose ($\mu g.kg^{-1}$) Propofol dose ($mg.kg^{-1}$) End-tidal sevoflurane at device insertion (%)	 1.03 (0.3) 2.62 (0.93) 3.58 (1.04)
Duration of procedure (min) Anaesthesia Surgery Ventilation	 51.3 (32.8) 42.7 (31) 36 (24.5)

Note: Data are reported as mean (SD), median (interquartile range, [range]) or as number (percentage).

Table 5.4. Relationship between patient characteristics and size of Baska™ mask placed successfully

	Size 4 (n=1)	**Size 5** (n=15)	**Size 6** (n=10)
Weight (kg)	72	84 (7)	94 (16)
Height (cm)	177	175 (7)	180 (7)
BMI ($kg.m^{-2}$)	23	27 (3)	29 (4)
Ideal Body Weight (kg)	71	69 (6)	73 (6)
Thyromental distance (cm)	8	7.9 (1.3)	7.7 (0.9)
Inter-incisor distance (cm)	5	5.4 (1.2))	4.8 (0.8)
Age (years)	26	57 (18)	59 (15)

Note: Data are reported as mean (SD)

As only one patient had a size 4 Baska™ mask successfully placed, data in this subgroup may not be representative.

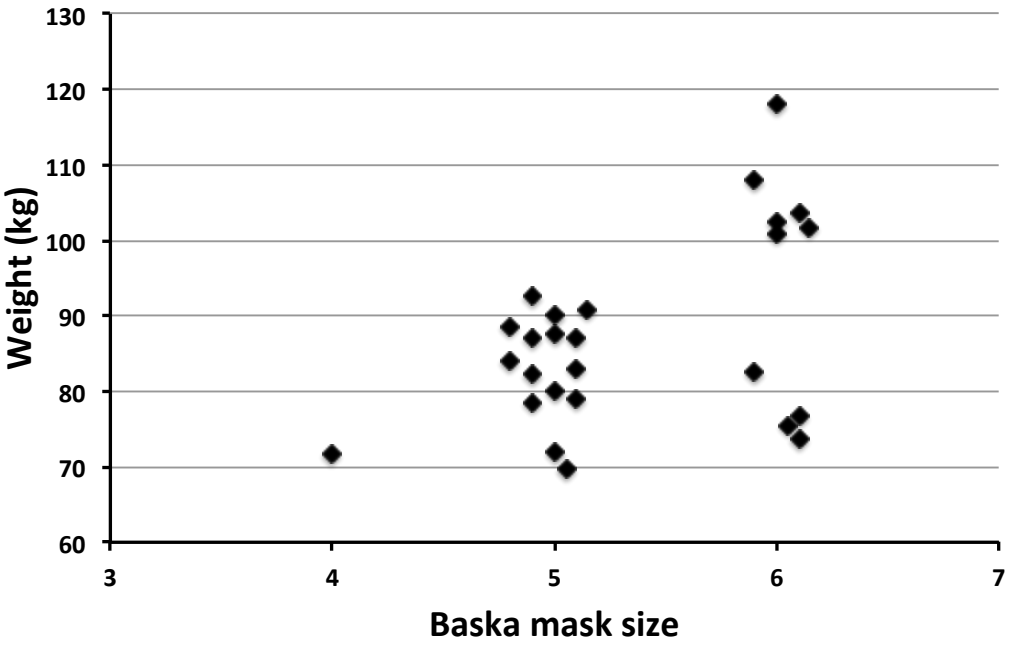

Figure 5.2. Scatter plot illustrating the Baska™ mask size successfully used in individual patients and their weight.

Note: Each dot represents an individual patient; the Baska™ mask size is displayed on the horizontal axis; the weight is displayed on the vertical axis in kg.

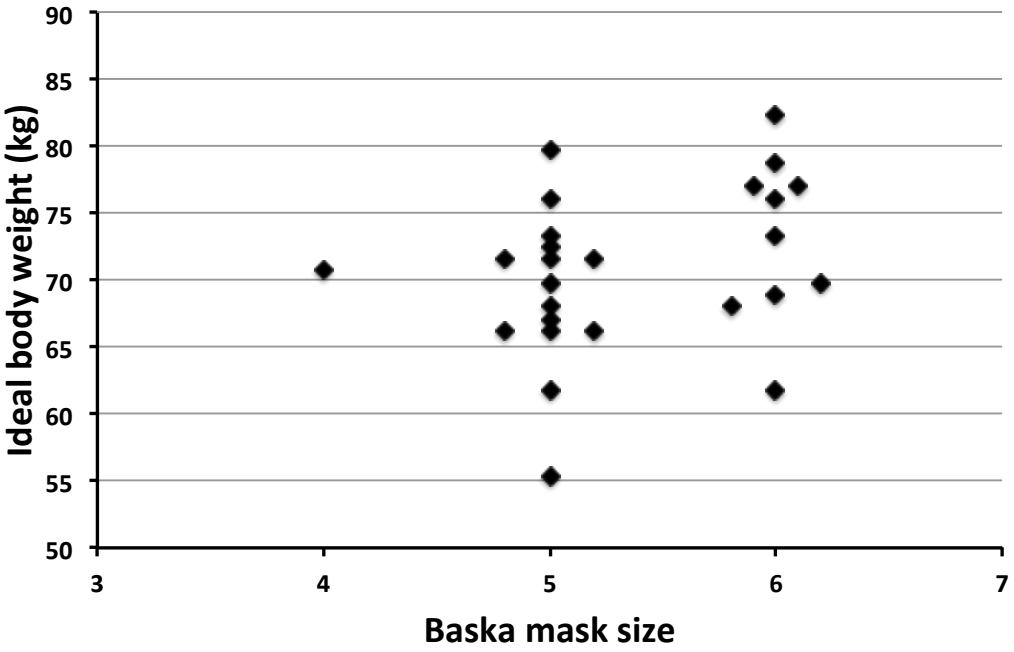

Figure 5.3. Scatter plot illustrating the Baska™ mask size successfully used in individual patients and their ideal body weight.

Note: Each dot represents an individual patient; the Baska™ mask size is displayed on the horizontal axis; the ideal body weight is displayed on the vertical axis in kg. Ideal weight in kg = 50 + (height in cm – 154) * 0.9

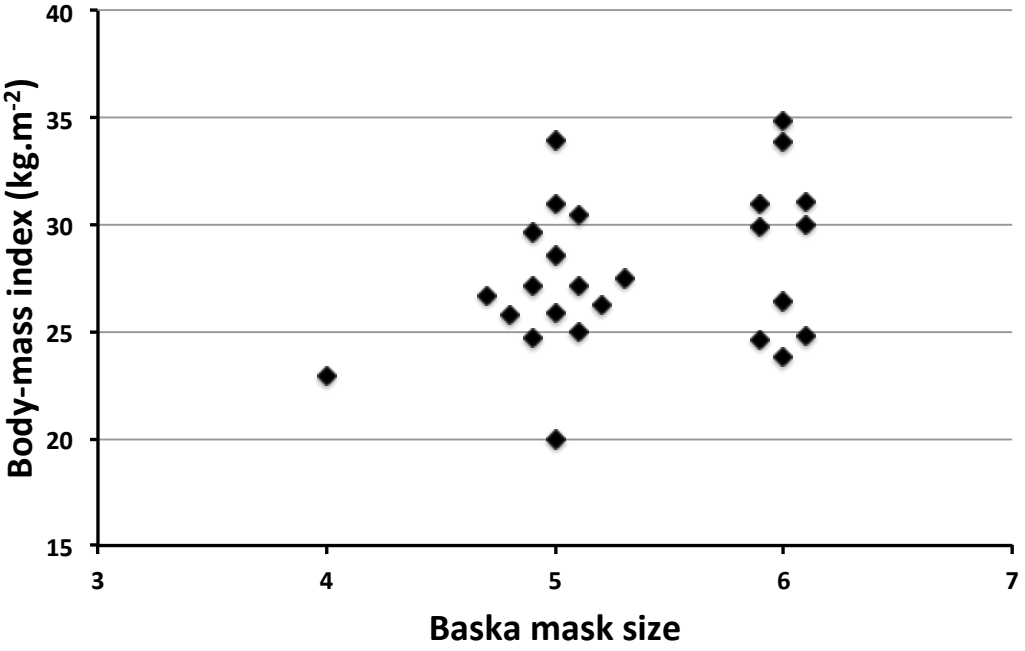

Figure 5.4. Scatter plot illustrating the Baska™ mask size successfully used in individual patients and their body-mass index

Note: Each dot represents an individual patient; the Baska™ mask size is displayed on the horizontal axis; the body-mass index (BMI) is displayed on the vertical axis. BMI= weight in kg / (height in m * height in m)

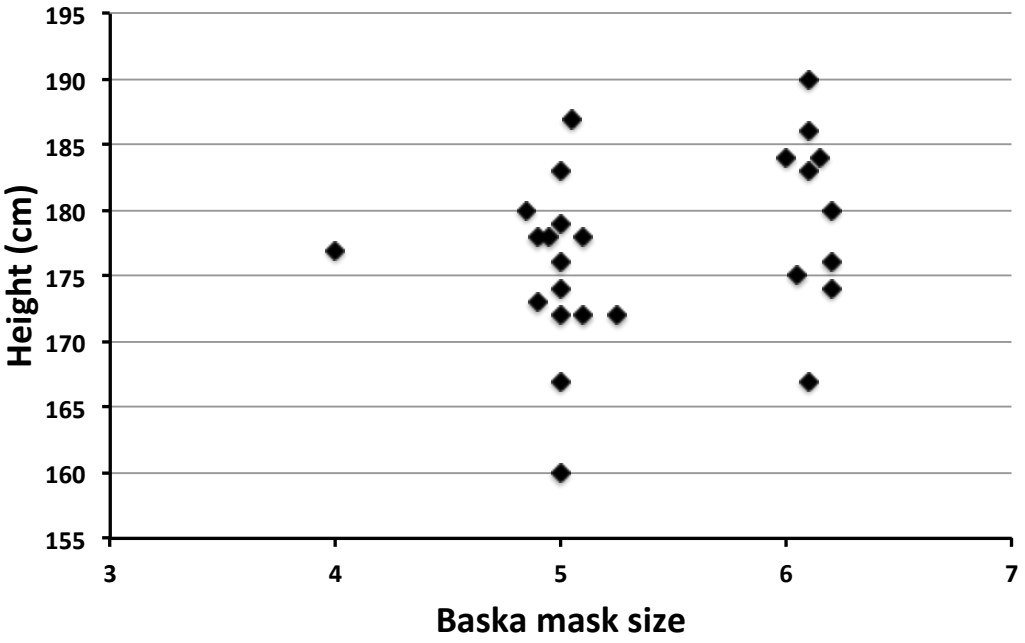

Figure 5.5. Scatter plot illustrating the Baska™ mask size successfully used in individual patients and their height

Note: Each dot represents an individual patient; the Baska™ mask size is displayed on the horizontal axis; the height is displayed on the vertical axis in cm.

5.3.4. Baska™ Mask Performance Characteristics

Intraoperative device performance data are presented in Table 5.5.

The mean (SD) airway leak pressure was 32.8 (7.5) cm H_2O. In 11 (39%) patients the airway leak pressure was less than 30 cm H_2O.

In 14 out of the 26 patients (54%) in which the Baska™ mask was successfully placed, there was an audible leak present immediately after the insertion. The leak disappeared after 5 minutes in 10 (71%) of these patients, suggesting that the cuff seal improves over time.

In three patients the mask position had to be adjusted intraoperatively (one episode was due to airway manipulation related to the study), in one of these we had to replace the Baska™ mask with an LMA.

5.3.5. Baska™ Mask Complications and Patient Comfort Indices

Data regarding complications and patient comfort indices are displayed in Table 5.5 and Table 5.6.

None of the patients experienced laryngospasm on emergence. While there was blood staining on mask removal in 8 patients (29%), the incidence of throat pain, dysphonia and dysphagia up to 3 days postoperatively was low (Table 5.6).

5.3.6. Learning Effect

Our data indicate the presence of a learning effect. The difficulty of insertion scores decreased during the course of the trial (Figure 5.6). In contrast, the seal pressures achieved did not show an upward or downward trend, suggesting correct position was achieved in all placements deemed to be successful (Figure 5.7).

Table 5.5. Data regarding device performance and complications

Airway leak pressure; cm H_2O	32.8 (7.5)
Ventilatory parameters	
Peak airway pressure; cm H_2O	18 (3.3)
Inspiratory volume; ml	553 (56)
Leak volume; ml	60 (62)
Peripheral oxygen Saturation during Attempt; %	
Lowest oxygen saturation	98 (1.4)
Number of patients with SpO_2 < 90%	0 (0)
Need to reposition/replace mask intraoperatively	3 (11%)
Complications; number (%)	
Laryngospasm	0 (0)
Blood-staining on mask removal	8 (29%)
Lip Injury	0 (0)

Note: Data are reported as mean (SD) or as number (percentage).

Table 5.6. Data regarding patient comfort indices

Severity of throat discomfort (VRS Score, 0-10)	
On arrival in PACU	0 (0,0 [0,2])
On discharge from PACU	0 (0,0 [0,2])
1st postoperative day	0 (0,0 [0,3])
3rd postoperative day	0 (0,0 [0,1])
Severity of dysphagia (VRS Score, 0-10)	
On arrival in PACU	0 (0,0 [0,3])
On discharge from PACU	0 (0,0 [0,3])
1st postoperative day	0 (0,0 [0,4])
3rd postoperative day	0 (0,0 [0,2])
Severity of dysphonia (VRS Score, 0-10)	
On arrival in PACU	0 (0,0 [0,0])
On discharge from PACU	0 (0,0 [0,0])
1st postoperative day	0 (0,0 [0,3])
3rd postoperative day	0 (0,0 [0,3])

Note: Data are reported as median (interquartile range, [range]).

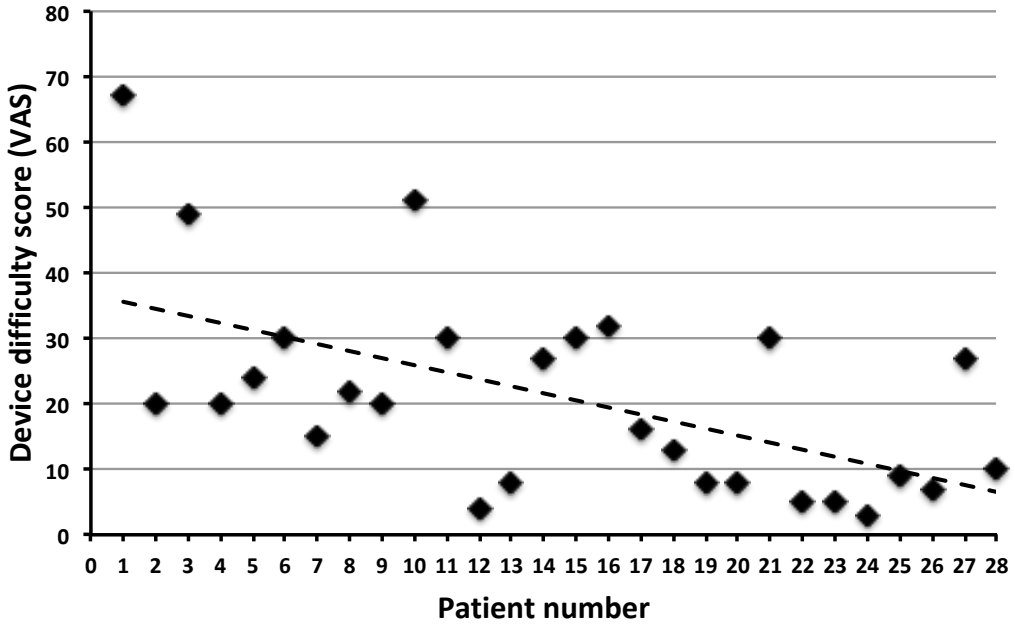

Figure 5.6. Scatter plot depicting device difficulty scores reported on consecutive patients

Note: The vertical axis represents the device difficulty score on a 100 mm visual analogue scale (VAS). The horizontal axis represents consecutive patients. The dash line represents a trend line.

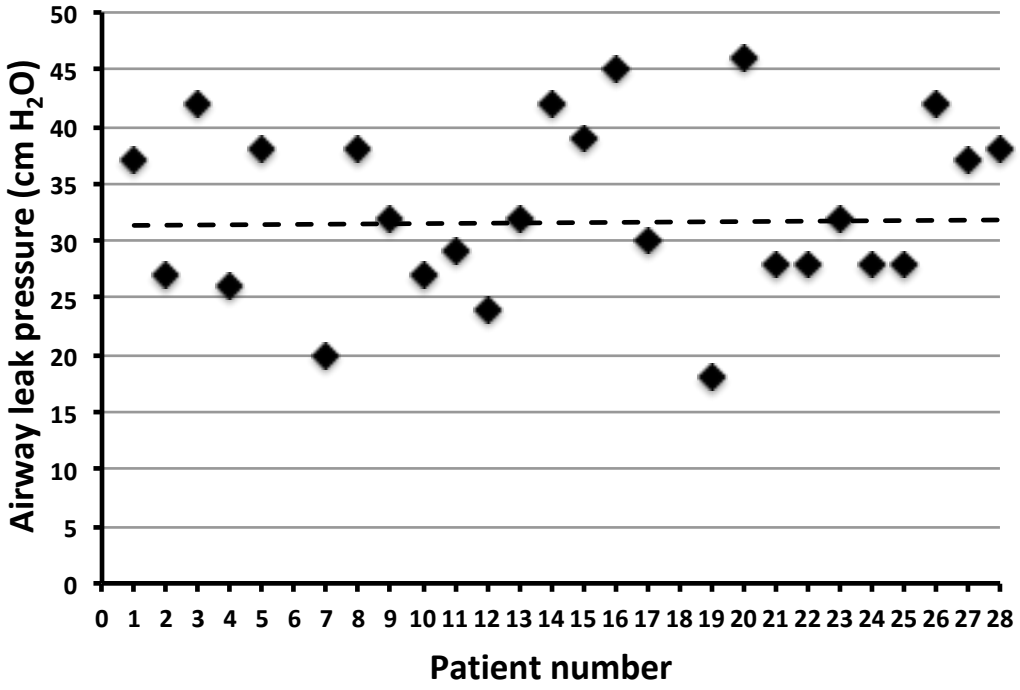

Figure 5.7. Scatter plot depicting airway leak pressures in consecutive patients

Note: The vertical axis represents the Baska mask airway leak pressure in cm H_2O. The horizontal axis represents consecutive patients. Baska mask was not placed successfully in patients 6 and 18, thus their airway leak pressure values are not presented. The dashed line represents a trend line.

5.4 Discussion

5.4.1. Baska™ Mask Insertion

The device insertion success rates in this study are lower than those we observed in female patients [53, 106]. Possible explanations include a learning effect as described in section 5.4.4 or a mismatch between the Baska™ mask cuff shape and/or size and the patients' anatomy.

5.4.2. Baska™ Mask Size and Performance

Our data demonstrate a trend towards larger size mask in patients with higher weight or height but unambiguous guidance could not be derived. Other anthropometric indices (age, BMI, ideal weight, inter-incisor or thyromental distance) did not appear to be more helpful either. Using the criteria defined in our study, size 5 Baska™ mask was successful in over half of cases. There may be an argument to use a size 5 mask initially except in taller or heavier males where a size 6 may be the first choice.

Other studies [53, 106, 117] demonstrated the Baska™ mask airway seal is consistently above 30 cm H_2O. In the current study the airway seal was less than 30 cm H_2O in 11 (39%) patients, which may suggest either poor fit or under sizing. If a larger mask size (limited to maximum size 6) had been used in each of these cases then 79% of all patients would have had a size 6 mask placed. The projected increase in the use of size 6 masks was not confined to the taller patients.

Given the above we suggest using either size 5 or 6 Baska™ mask in males of average height and weight, and size 6 in heavier/taller males until further experience is accumulated.

We successfully used a size 4 Baska™ mask in only one patient. This does not allow for any conclusions to be drawn regarding the role of size 4 masks in male adults. Nevertheless the fact that size 5 and 6 masks were used

successfully in the majority of our patients indicates that size 4 masks are unlikely to have significant role in males.

5.4.3. Baska™ Mask Complications

In 3 patients of the 26 (11.5%) in whom Baska™ mask was successfully placed we had to adjust the mask position or place an alternative airway device intraoperatively. This is an important finding. There are many possible explanations including lack of experience in male patients, poor fit of the mask in the pharynx (the mask has pre-formed shape), inappropriate size selection, or poor alignment of the relatively small cuff orifice against the glottis. This finding is in contrast with our experience with the use of the mask in female patients where the intraoperative performance was more reassuring [53, 106]**.** The incidence of throat pain, dysphagia and dysphonia was low despite the high incidence of blood staining on mask removal.

5.4.4. Learning Effect

While both operators had extensive previous experience in Baska™ mask use (mostly in female patients) our data indicate the presence of a learning effect. The difficulty of insertion scores decreased during the course of the trial (Figure 5.6). In contrast, the seal pressures achieved did not show an upward or downward trend, suggesting correct position was achieved in all placements deemed to be successful (Figure 5.7).

5.4.5. Study Limitations

Our study has limitations. The sample size was too small to draw statistically relevant conclusions and should be used rather as a basis for future studies. The study was not blinded so patient as well as investigator bias was possible. The learning effect indicated by the evolution in the operator - rated device difficulty scores may have affected our other findings. In this study we used established criteria for successful device insertion (see Section 5.2.5) [52, 87]. Furthermore we introduced a requirement for the airway leak pressure to be at least 15 cm H_2O – a value that would be considered acceptable for the cLMA [99]. At the time of the design of this study we could not justify using specific higher value. In

hindsight the cut-off value used was too low as subsequently published results indicate that the Baska mask demonstrates airway leak pressures consistently above 30 cm H_2O [53, 106, 117, 118]. The relatively low airway leak pressures in this study indicate possible mask under-sizing in significant proportion of our patients. Possible way to verify this hypothesis would be to perform a study where multiple device sizes are attempted in each patient and various performance parameters are evaluated (e.g. airway leak pressure, leak fractions etc.).

5.5. Conclusions

In our study the manufacturer's original weight-based sizing guidelines were associated with high first insertion attempt failure rates. Our results suggest that using a size 6 Baska™ mask in male patients of weight above 90 kg or of height above 180 cm may be an appropriate strategy. In males with approximate weight 70 to 90kg or height 170 to 190 cm either size 5 or 6 Baska™ mask may be appropriate. The airway leak pressures observed were high, in line with previous studies of the Baska™ mask [53, 106, 117] and indicate a superior airway seal. The incidence and the severity of postoperative sore throat, dysphagia and dysphonia were low. The first time and overall insertion success rates were low (76.7% resp. 93%), but this data has to be interpreted with caution as the device is new and the optimal sizing strategy and insertion technique has to be determined. Intraoperative mask position adjustment/device change rate was high underlying the need for further evaluation of this device in order to determine the safety profile in the male population. Based on our results we feel more rigid definition for device success rate (i.e. leak fraction of less than 20% and a reasonable airway leak pressure) may be useful when evaluating SAD sizing strategies.

6. An Observational Study of the Baska™ Mask in Children

6.1. Introduction

Supraglottic airway devices are well established in the paediatric anaesthesia practice [119]. The Baska™ mask is a new supraglottic airway device which we have evaluated in adult patients [53, 106, 120]. To our knowledge the Baska™ mask performance and safety profile in children has not been examined previously. In this study we planned to perform a pilot evaluation of this device in low risk paediatric patients. The objective of the study was to accumulate initial information regarding Baska™ mask insertion success rates, ease of use and speed of insertion, performance during general anaesthesia and the rate of complications.

6.2. Methods

6.2.1. Patient Selection

This observational study was approved by the Galway University Hospitals Research Ethics Committee (Ref. C.A. 657). Following written informed parent/guardian consent and when appropriate, patient assent, we studied 20 patients. The inclusion and exclusion criteria are presented in Table 6.1.

Table 6.1. Patient inclusion and exclusion criteria.

Included	Excluded
• Age 8-16 years or Weight ≥ 30 kg • ASA class 1-2 • Low risk of difficult intubation • BMI 15-35 $kg.m^{-2}$ • Non-urgent surgery of planned duration ≤ 2 hrs.	• Known/anticipated problems with: - upper airway - upper GI tract • Neck pathology • Increased risk of gastric aspiration

6.2.2. General Anaesthesia

Standard monitoring included ECG, pulse oximetry, non-invasive blood pressure, ventilation volume, airway pressure and end-tidal gas monitoring. Intravenous access was secured. The patients were preoxygenated. Sleep dose of propofol (3-5 $mg.kg^{-1}$) was titrated to induce anaesthesia and ensure jaw relaxation. The patients were ventilated with 100% O_2 and end-tidal sevoflurane of 2-4%.

6.2.3. Baska™ Mask Insertion

All device insertions were performed by one investigator (VA) with prior experience with Baska™ mask use in adult patients [53, 106, 120]. This investigator had not used the device in children previously. Given the fact we studied paediatric population we used more conservative strategy as compared with our studies in adults. Maximum of 2 insertion attempts were allowed per patient (compared with 3 attempts in our adult studies). The Baska™ mask size choice for the first insertion attempt was based on the manufacturer's guidelines [57] (Table 3.2).

If the device did not function properly the following manipulations were performed in a sequence: the device was pushed further in, rotated and withdrawn slightly. If an effective airway was not achieved, the device was removed. If the problem was deemed to be due to a large leak, a device one size bigger was used during the following attempt. If the device was deemed too large, as evidenced by difficulty in advancing it into the pharynx and in ventilating the patient, a device one size smaller was inserted. Following 2 failed insertion attempts a laryngeal mask airway was inserted.

6.2.4. Maintenance of Anaesthesia

Once the airway was secured, mechanical ventilation was maintained until spontaneous ventilation supervened. Anaesthesia was provided with sevoflurane in a mixture of oxygen and air. Further management (including

opioid administration after the study measurements were performed) was left to the discretion of the primary anaesthetist.

6.2.5 Data Collection

All device insertion - related data were collected by an unblinded observer. "Duration of device insertion attempt" was defined as the time from the moment the device was touched by the operator until successful ventilation was achieved or the device was removed [103, 104]. "Successful ventilation" was defined as the presence of bilateral chest expansion and a satisfactory end-tidal carbon dioxide tracing with a plateau [52, 87]. The device insertion data collected are listed in Table 3.3. Failure to place the device was scored as 100 on the VAS difficulty score.

6.2.6. Baska™ Mask Leak Test

After adequate ventilation was ensured a leak test was performed [86, 87, 121]. While the patient was apnoeic, the adjustable pressure-limiting valve was closed to 35 cm H_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 35 cm H_2O the leak test was immediately interrupted and a value of 35 cm H_2O was recorded. Again, to enhance safety, in this paediatric study we adopted a more conservative approach to the airway leak testing. In our studies on adults we used a plateau pressure cut-off of 40 or 50 cm H_2O [53, 106, 120].

The stability of the placement of the Baska™ mask was assessed by determining the leak fraction while the patient received volume controlled ventilation with inspiratory volume 6-10 $ml.kg^{-1}$ in four different head positions: neutral; rotated to right; head extended; and without pillow. A leak fraction was calculated according to the formula: $[V_{insp} - V_{exp}]/V_{insp}$ x 100.

6.2.7. Data Regarding Complications

The following complications were specifically monitored: presence of abdominal distension; arterial oxygen desaturation; lip or teeth damage; blood staining on mask removal; cough; and laryngospasm. We recorded the incidence and severity of sore throat at discharge from the recovery room using a paediatric visual analogue scale (VAS).

6.2.8. Sample Size

We planned to enrol a minimum of 20 and a maximum of 30 patients. Once 20 patients were recruited, an independent observer would examine the data and assess for fulfilment of a predefined set of stopping criteria (Figure 6.1). These included: 1. insertion on first attempt; 2. insertion duration of less than 30 seconds; 3. leak fraction less than 20% in a neutral head position. If all of these criteria were not fulfilled in 5 consecutive patients, we would continue recruiting in batches of 5 patients until the stopping rule was fulfilled or until 30 patients were recruited.

Parametric data are reported as mean and standard deviation, non-parametric data as median and interquartile range or number and percentage.

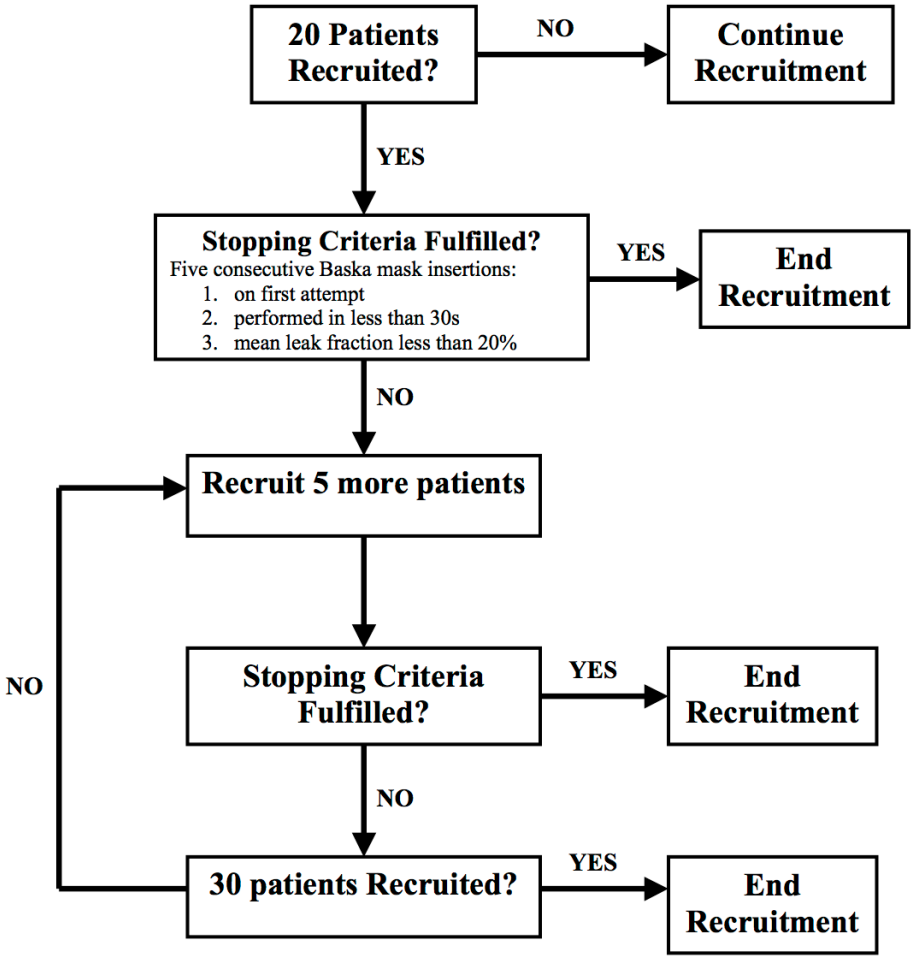

Figure 6.1. Patient recruitment flowchart

6.3. Results

Twenty patients were recruited. Of the 22 patients assessed for eligibility one was excluded due to a lack of consent and the other due to surgeon's request for endotracheal tube placement. After 20 patients were studied enrolment was ended as the stopping criteria were fulfilled.

6.3.1. Patient Demographics

The patient characteristics are displayed in Table 6.2. The patient population consisted of 9 females (aged 7-14 years) and 11 males (aged 9-16 years). The patients were low risk, of ASA class 1-2, and all had a BMI below 25 $kg.m^{-2}$. The history and airway assessment were not predictive of airway management difficulties and all had a Mallampati score below 3. Ten (50%) of our patients underwent ENT procedures (mostly grommet insertion), 6 (30%) had orthopaedic surgery (e.g. k-wire insertion or removal) and the remainder had other minor procedures. In 4 patients (20%) the anaesthetic time exceeded 1 hour (76 – 123 minutes). On average the patients underwent controlled ventilation for 85% of the total anaesthetic time (Table 6.3).

Table 6.2. Characteristics of the patients enrolled in the study

Number of Patients	20
Female	9
Male	11
Age (years)	9.5 (9-13 [7-16])
Anthropometric parameters:	
Height (cm)	149 (132-159 [130-185])
Weight (kg)	39.4 (32.2-51.5 [23.5-69])
Body Mass Index ($kg.m^{-2}$)	18.5 (2.5)
ASA Classification	1 (1-1 [1-2])
Mallampatti Classification	1 (1-2 [1-2])
1	10 (50%)
2	8 (40%)
not recorded	2 (10%)
Type of Surgery	
ENT	10 (50%)
Orthopaedic	7 (35%)
Other	3 (15%)

Note: Values are reported as median (IQR [range]) or number (proportion).

6.3.2. Baska™ Mask Insertion and Mask Size

The anaesthetic management and device insertion data are presented in Table 6.3. Baska™ mask was placed successfully on 1st attempt in 17 of 20 patients (85%, 95% confidence interval 69-100%). In 2 patients (10%) the mask was inserted successfully on 2nd attempt. Alternative device (LMA) was placed in one patient. The overall insertion success rate for the Baska™ mask was 95% (95% confidence interval 76-100%).

The mean (SD) duration of the first insertion attempt was 29.1 (17.1) s. The mean (SD) duration of the successful Baska™ mask insertion attempt was 26 (15.9) s. The insertion duration data are displayed in Figure 6.2 and Figure 6.3.

In 15 (75%) of the patients optimisation manoeuvres (device pushed further in, rotated or withdrawn slightly) were required during the mask insertion.

Baska™ mask size 3 was inserted successfully in 14 patients (70%). The patients in this group were of age 7 to 14 years, had weight 23.5 to 53 kg and height 130 to 165 cm. The group where Baska™ mask size 4 was placed consisted of five patients (25%), aged 12 to 16 years, with weight of 49.5 to 69 kg and height of 155 to 185 cm.

Table 6.3. Data regarding device insertion and anaesthetic management.

Overall success rate	19/20 (95%)
Success rate	
First insertion attempt	17 (85%)
Second insertion attempt	2 (10%)
Failure rate	1 (5%)
Duration of insertion attempts (s)	
First insertion attempt	29.1 (17.1)
Successful insertion attempt	26 (15.9)
Size of Baska™ mask inserted	
3	14 (70%)
4	5 (25%)
Device difficulty score (VAS Score, 0-100 mm)	11.5 (4-25 [0-100])
Induction of anaesthesia	
Propofol dose ($mg.kg^{-1}$)	4.1 (1.2)
End-tidal sevoflurane at insertion (%)	4.3 (1.2)
Duration of procedure (min)	
Anaesthesia	36.6 (31.3)
Surgery	30.2 (30.8)
Controlled ventilation	31.2 (5.9)

Note: Values are reported as mean (SD), median (inter-quartile range [range]) or number (percentage).

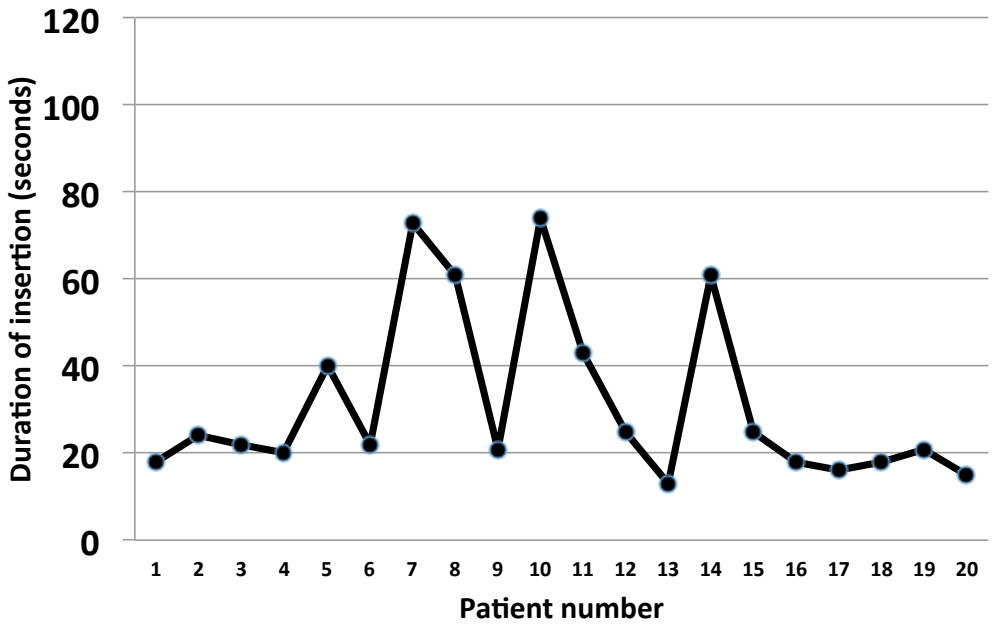

Figure 6.2. Graph depicting the duration of Baska™ mask insertion attempts in subsequent patients.

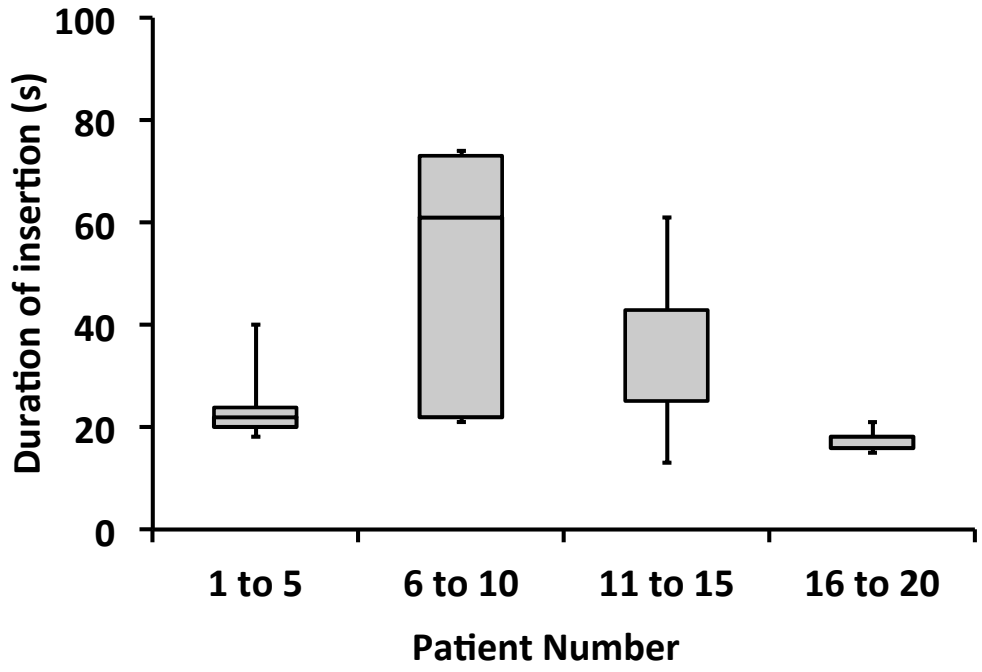

Figure 6.3. Graph illustrating the duration of the Baska™ mask insertion attempts for subsequent groups of five patients.

Note: The bottom and top of the box represent the first and third quartiles, the band inside the box represents the median value, the whiskers represent the range. In the 3rd group of patients the median and the second quartile are superimposed. In the 4th group the median and the third quartile are superimposed. The median values in the 1st, 3rd and 4th group are comparable, approx. 20 s.

6.3.3. Baska™ Mask Performance Characteristics

The median [IQR] airway leak pressure was 35 [27-35] cm H_2O in the patients in whom the Baska™ mask was inserted successfully. The leak test upper limit of 35 cm H_2O was reached in 13 (65%) of the patients. The airway leak test data are displayed in Figure 6.4 and Figure 6.5. An audible leak during positive pressure ventilation immediately after mask placement was present in 14 (70%) patients (Table 6.4). It disappeared after 5 minutes in all cases. This suggests that the cuff seal improves over time and is in line with the findings of our previous studies [53, 106, 120].

The leak fractions in four different head positions are shown in Table 6.4. The median leak fraction increased from 10.6% in neutral head position to 13.6% following head rotation.

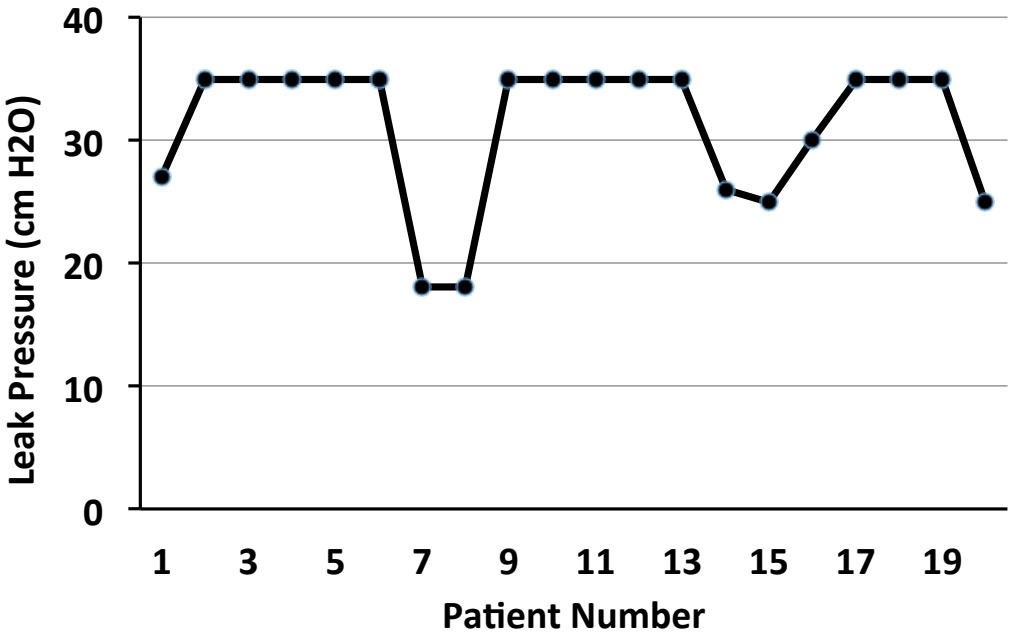

Figure 6.4. Graph of the Baska™ mask leak pressures in subsequent patients.

Note: The leak test was interrupted if the airway pressure reached 35 cm H_2O and a value of 35 cm H_2O was recorded for the respective patient.

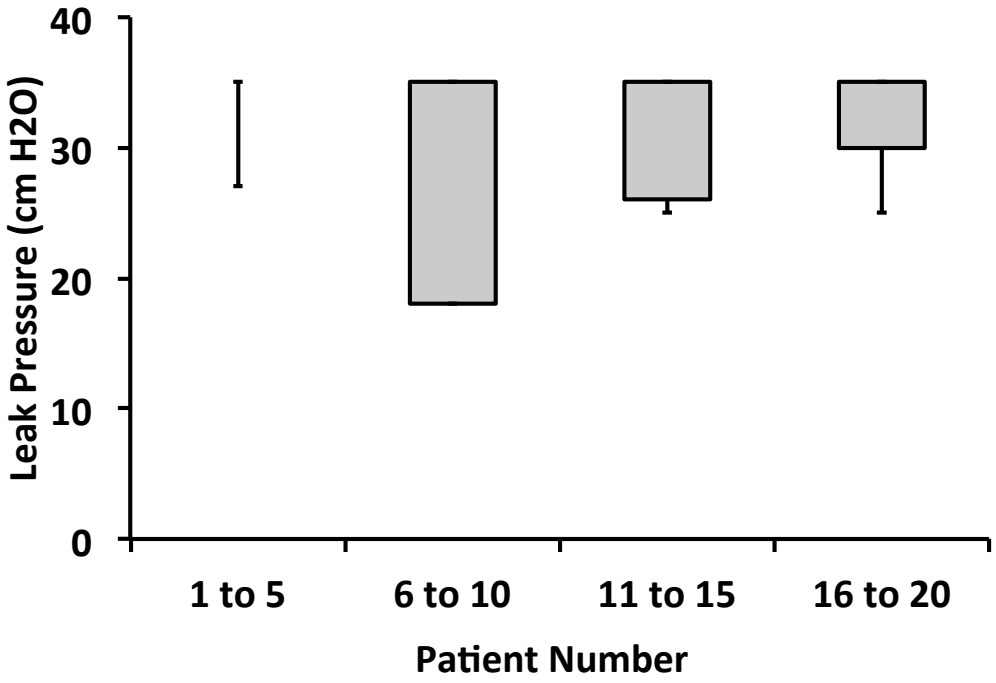

Figure 6.5. Graph depicting the Baska™ mask leak pressures in subsequent groups of 5 patients.

Note: The bottom and top of the box represent the first and third quartiles, the band inside the box represents the median value, the whiskers represent the range. In the first group the median and the interquartile range were 35 cm H_2O. In the last 3 groups of patients the median and the 3rd quartile are superimposed.

Table 6.4. Data regarding device performance

Leak pressure; cm H_2O	35 (27-35 [18-35])
Patients with audible leak at 0 min after device placement at 5 min after device placement	 14 (70%) 0
Measured mask leak (%) Supine Head rotated Head extended No pillow	 11 (6-13 [1-23]) 14 (7-17 [3-24]) 14 (10-19 [2-55]) 13 (11-23 [5-85])
Peripheral oxygen saturation during attempt (%) Lowest oxygen saturation during attempt: Number of patients with SaO2 < 90%	98.75 (0.7) 97% 0

Note: Values are reported as mean (SD), median (IQR [range]) or number (proportion).

6.3.4. Baska™ Mask Complications

The data regarding complications and comfort indices are presented in Table 6.5. There were no episodes of arterial oxygen desaturation during device placement or intraoperatively. No instances of gastric distension were observed. Three patients (15%) experienced coughing on mask removal at emergence. Two of these patients (10%) proceeded to laryngospasm, which was managed conservatively. In 4 patients (20%) we observed mild to moderate blood staining on mask removal. No lip or dental injuries were observed. Nine patients (45%) reported sore throat in recovery, but only 3 of them (15%) rated this at 4 or more on a 0-10 visual analogue scale.

6.4.5. Baska™ Mask Insertion Difficulty

The median [IQR] operator-rated device difficulty score was 11.5 [4-25] on a 100 mm VAS scale. Score data are shown in Figure 6.6 and Figure 6.7. The device difficulty scores recorded for subsequent patients were not suggestive of a learning effect.

Table 6.5. Data regarding device complications

Complications	
Gastric distension	0
Cough	3 (15%)
Laryngospasm	2 (10%)
Bleeding (mask stained on removal):	
Minor	2 (10%)
Moderate	2 (10%)
Severe	0
Lip or dental injury	0
Throat discomfort on PACU discharge (VAS Score, 0-10)	0 (0-2.5 [0-6])

Note: Values are reported as median (IQR [range]) or number (proportion).

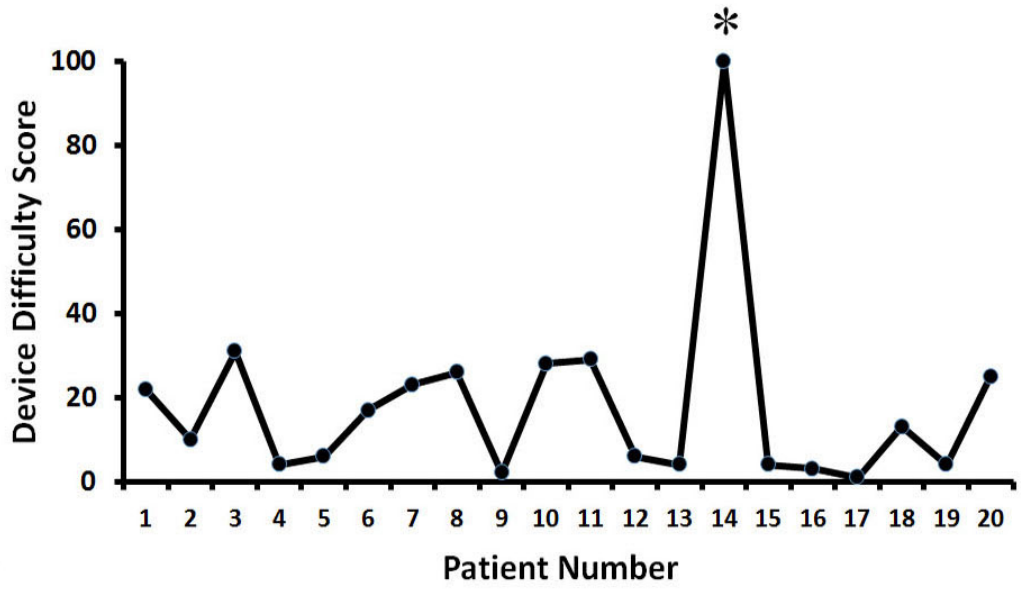

Figure 6.6. Graph demonstrating device difficulty scores in subsequent patients.

Note: The score was operator-rated using a 100 mm visual analogue scale.
***** denotes a patient in whom Baska™ mask placement failed.

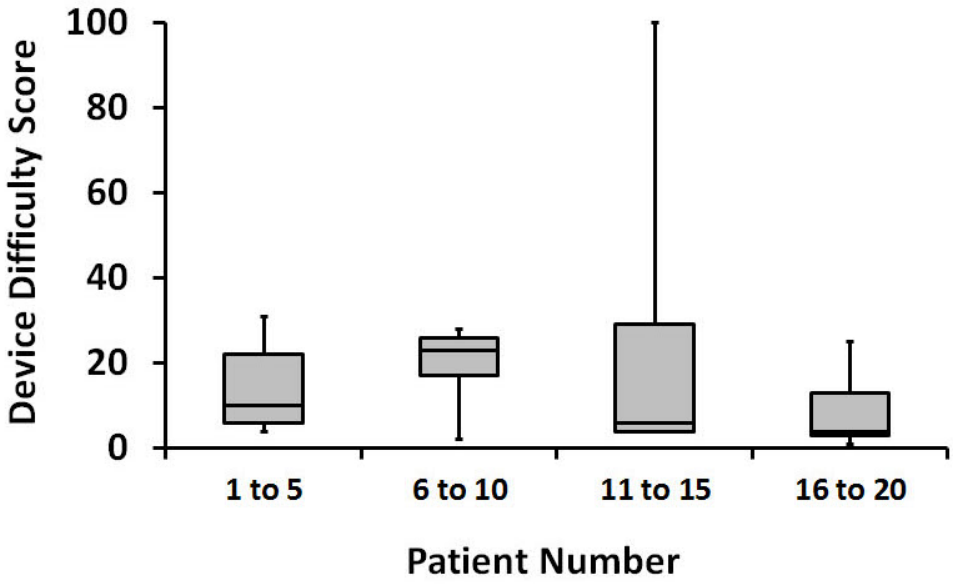

Figure 6.7. Graph depicting device difficulty scores in subsequent groups of five patients.

Note: The bottom and top of the box represent the first and third quartiles, the band inside the box represents the median value, the whiskers represent the range.

6.4. Discussion

Our study represents the first report, to our knowledge, of Baska™ mask use in the paediatric population.

6.4.1. Baska™ Mask Success Rates

The observed overall insertion success rate of 95% is in line with our previous studies in adult females [53, 106] but higher than the rate we observed in adult male patients [120]. For comparison, in studies evaluating the LMA Supreme™, LMA ProSeal™ and i-gel® in children, Jagannathan et al. and Beringer et al. report overall insertion success rates respectively 100%, 100% and 99% [122, 123].

While we found an overall device insertion failure rate of 5%, the upper range of the 95% confidence interval was 24%. This is not surprising given our small sample size, and warns against applying our data to argue for or against the use of the device in routine clinical setting [114]. Our results rather may facilitate the design of an adequately powered RCT on a well-matched (in terms of age, sex, airway characteristics, body habitus, surgery type etc.) paediatric population.

6.4.2. Baska™ Mask Size

Baska™ mask size 3 performed reasonably well in our small cohort despite the anticipated variability in airway dimensions in the paediatric population. As may be expected, patients of higher age and height were more likely to require a larger mask size. Size 3 Baska™ mask was used in all patients younger than 12 years of age. In patients of age 12 to 14 years we successfully used both size 3 and size 4 masks. The manufacturer guidance on mask sizing seemed to work reasonably well in our patient population. There were three instances where a mask of a size different to the recommended was used. These patients had a weight of 49.5-53 kg which is perfectly acceptable given the manufacturer's recommended cut off of 50kg between Baska™ mask size 3 and size 4.

6.4.3. Baska™ Mask Airway Seal

The airway leak pressure in our paediatric patients (median 35 cm H_2O) compares favourably with the results published for other supraglottic devices used in the paediatric population: a median 19 cm H_2O for LMA Supreme™ [123]; median 18 cm H_2O for LMA ProSeal™ [123]; and a median 20 cm H_2O for i-gel [122]. Our results likely underestimate the true Baska™ mask airway leak pressure, as the leak test was limited to 35 cm H_2O and this value was reached in 13 (65%) of the studied patients. These results are in line with studies of the Baska™ mask we conducted in adult patients [53, 106, 120] and indicate that the Baska™ mask has a superior airway seal. Given the differences in the airway leak tests used in the various studies (maximum airway pressure allowed, equipment used, fresh gas flow rate) this observation should interpreted with caution.

The Baska™ mask has a small cuff orifice that requires sufficient alignment with the glottis. This notion is supported by the fact that optimisation manoeuvres were required in 15 patients (75%). Furthermore, the airway seal seems to improve over time. The audible leak present immediately after Baska™ mask placement in 14 (70%) of the patients disappeared in all after 5 minutes. The improvement in the seal may be secondary to cuff expansion, caused by the positive pressure applied during the airway leak test and the controlled ventilation. We reported similar findings in our studies on adult patients [53, 106, 120].

The manufacturer's guidelines recommend using a size 3 Baska™ mask in patients with a weight of 30 to 50 kg [32]. This weight range corresponds to a wide age range in the paediatric population. Accordingly, significant variation in the pharyngeal dimensions would be expected. We used more liberal mean leak fraction (namely 20%) in our study stopping rules as compared with our studies in adult females [53, 106] to accommodate for this variability and the anticipated variability in the quality of the airway

seal. Our results support this assumption with leak fractions (Table 6.4) higher than the values we recorded in our trials on adults [53, 106, 120].

6.4.4. Learning Effect

There was no indication of a learning effect in the airway leak or the device difficulty scores data in consecutive patients (Figures 6.4, 6.5, 6.6 and 6.7). One might argue that there was an improvement in the device insertion times, yet the median insertion times in the first, third and fourth group of 5 consecutive patients were similar around 20 s (Figures 6.2 and 6.3).

6.4.5. Baska™ Mask Complications

The incidence of laryngospasm on emergence (10%), blood staining on mask removal (20%) and postoperative throat discomfort (40%) in our study was higher than the incidence reported for other supraglottic airway devices in paediatric patients [119]. For instance, Beringer et al. report an incidence of postoperative sore throat of 3-13% [122, 124] and incidence of blood staining 0-6% for other supraglottic airway devices [122] . The fact that in our study half of the patients underwent ENT procedures may have contributed to the higher incidence of upper airway complications.

6.4.6. Study Limitations

Our prospective cohort study has limitations. The sample size was small thus the confidence intervals for our results are large. One experienced anaesthesiologist placed all devices. The observed device success rates, incidence of complications and patient comfort indices should be interpreted accordingly and used only as pilot data [114]. As in our previous studies [53, 106, 120], the proportion of time the patients underwent controlled ventilation was high and further focussed evaluation on spontaneously breathing patients is needed. We intended to accumulate initial device performance and safety data in paediatric patients. The study design does not allow for the results to be used to justify use in routine clinical practice [106, 114]. Investigator bias was possible. The device

difficulty score and the throat discomfort score are subjective thus open to bias.

6.5. Conclusions

Our results of the use of the Baska™ mask on 20 low-risk paediatric patients aged 7 to 16 years demonstrated an encouraging device success rate and a high airway leak pressure, indicating good airway seal. The manufacturer sizing guidelines appeared to work well, and size 3 Baska™ mask was used successfully in all patients under 12 years of age. Our results have limitations and should be verified in a large RCT.

7. Fibreoptic Evaluation of the Baska™ mask in Anaesthetised Adult Patients

7.1. Introduction

SADs in situ interact with the surrounding anatomical structures. A sufficient degree of alignment of the airway device orifice with the laryngeal inlet and an adequate airway seal are prerequisites for successful ventilation. Furthermore SADs undergo conformational changes following placement inside the pharynx. For instance the sides of the i-gel bowl bend inwards resulting in increased anterio-posterior bowl dimension [79].

As part of two studies of the Baska™ mask (see Chapters 4 and 5) [53, 120] we wished to evaluate visually the behaviour of this novel airway device in the pharynx. In this case series, we report the findings of fibreoptic evaluations of the Baska™ mask on 20 anaesthetised patients. We assessed the configuration of the Baska™ mask cuff in situ and its position in relation to the laryngeal inlet. In each patient, we compared our findings with device performance data (peak and plateau airway pressures during positive pressure ventilation, presence of audible leak, quality of airway seal, occurrence of complications etc.).

7.2. Methods

7.2.1. Patient Selection

Approval by the Galway University Hospitals Research Ethics Committee was obtained (Ref. C.A. 653 and C.A. 724). Following written informed consent we studied 20 adult patients. The inclusion and exclusion criteria are shown in Table 7.1.

Table 7.1. Study inclusion and exclusion criteria

Inclusion Criteria	**Exclusion Criteria**
▪ ASA physical status 1-3 ▪ Age 18-65 ▪ BMI ≤ 35 $kg.m^{-2}$ ▪ Non-urgent surgery of planned duration ≤ 4 hrs.	▪ Patients unwilling or unable to give consent ▪ Neck pathology ▪ Previous or anticipated problems with the upper airway or the upper gastrointestinal tract ▪ Live pregnancy ▪ Increased risk of gastric aspiration ▪ Predicted or previously documented difficult airway

7.2.2. General Anaesthesia

A standardised general anaesthetic was provided [101]. Standard monitoring was utilised throughout, including ECG, non-invasive blood pressure, pulse oximetry and end-tidal gas monitoring. Fentanyl or remifentanil (1-1.5 $\mu g.kg^{-1}$) was given intravenously. Sleep dose of propofol (2-4 $mg.kg^{-1}$) was titrated to induce anaesthesia and ensure jaw relaxation. Manual ventilation was commenced with sevoflurane or desflurane in oxygen. When needed the depth of anaesthesia was increased by means of additional propofol increments to facilitate Baska mask insertion.

7.2.3. Baska™ Mask Insertion

Four investigators (V. Alexiev, A. Ochana, J. Coyne, J. McDonnell) performed all device insertions in accordance with the manufacturer's instructions [53, 120]. Each had received instruction in Baska™ mask use and had performed over 30 insertions. Up to 3 Baska™ mask insertion attempts were permitted per patient. During the first insertion attempt the Baska™ mask size choice was based on the patient's weight as per manufacturer's instructions (Table 3.2). If the device did not function properly, the following manipulations were performed in sequence: the device was pushed further in, rotated and withdrawn slightly. If an effective airway was not achieved the device was removed. If the problem was deemed to be due to a large leak, a device one size smaller was inserted. If the device was deemed too large, a device one size smaller was inserted. A laryngeal mask airway (LMA) was to be used in the case of 3 failed Baska™ mask insertion attempts.

7.2.4. Maintenance of Anaesthesia

Once the airway was secured, mechanical ventilation was maintained until spontaneous ventilation supervened. Anaesthesia was provided with sevoflurane or desflurane in a mixture of air or N_2O and oxygen.

7.2.5. Data Collection

An unblinded observer collected all device insertion - related data. "Duration of device insertion attempt" was defined as the time from the moment the operator touched the device until successful ventilation was achieved or the device was removed [103, 104]. "Successful ventilation" was defined as the presence of bilateral chest expansion and end-tidal carbon dioxide tracing with plateau [52, 87]. The insertion data collected are listed in Table 3.3.

7.2.6. Baska™ Mask Leak Test

A leak test was performed [86, 87]. While the patient was apnoeic, the adjustable pressure-limiting valve was closed to 70 cm H_2O, the fresh gas flow was set at 6 $L.min^{-1}$, and the pressure was measured on the breathing circuit pressure gauge. "Leak pressure" was defined as the plateau airway pressure that was achieved. This case series includes pooled patients from two clinical trials (on male and female patients) where different leak pressure test stop rules were used. In the female patients in whom the airway pressure reached 40 cm H_2O the leak test was immediately interrupted as a safety precaution and a value of 40 cm H_2O was recorded. In the male patients we used a cut – off value of 50 cm H_2O.

The stability of the placement of the Baska™ mask was 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 without pillow. A leak fraction was calculated according to the formula: $[V_{insp}-V_{exp}]/V_{insp}$ x 100.

7.2.7. Fibreoptic Evaluation

One operator (VA) performed all fibreoptic examinations. After the airway leak and airway stability tests were completed an Ambu® Scope™ II (Ambu AS, Ballerup, Denmark) was advanced via the ventilation channel of the Baska mask. The analogue video signal from the Ambu® Scope™ II screen was digitalised using Canopus® ADVC 110 convertor (Grass Valley Group, Grass Valley, California, USA) and recorded on MacBook® 2.1 with iMovie® HD software (Apple Inc., Cupertino, California, USA). The video sequences were processed and analysed by one investigator (VA) on MacBook® Pro 9.1 and iMac 17.1, using iMovie® HD and QuickTime® (Apple, Cupertino, California, USA) and MPEG Streamclip™ (Squared 5, Rome, Italy) software.

We specifically looked at: (1) cuff alignment around the laryngeal inlet; (2) epiglottis position in relation to the Baska™ mask cuff; (3) findings suggestive of the cuff being either too shallow or too deep in relation to the

laryngeal inlet; (4) presence of cuff deformity, suggestive of the cuff being either too deep or too big for the size of the pharynx; (5) changes of cuff shape/position (i.e. cuff expansion; altered alignment around the laryngeal inlet) over time on subsequent fibreoptic scope passes; (6) blood staining. We looked for correlations between the cuff shape/position and some monitored parameters (peak airway pressures, airway leak pressures, blood staining on mask removal etc.). The criteria used during the analysis of the images are presented in Table 7.2. In addition we quantified the extent of visualisation of the glottic orifice using the percentage of glottic opening (POGO) score [125].

Table 7.2. Criteria used during the analysis of the fibreoptic images of the Baska™ mask.

Cuff alignment and contact with laryngeal inlet:

a. **Good:** the device cuff membrane is in continuous contact with the mucosa around the posterior commissure of the larynx and the aryepiglottic folds. The epiglottis is either within the cuff orifice or between the tongue base and the mask cuff. No cuff folding present.
b. **Satisfactory:** as above but minor cuff folding present.
c. **Poor:** none of above

Degree of cuff folding:

a. **None.**
b. **Minor:** Cuff membrane folding. No visible air tract deemed to have potential to compromise the airway seal.
c. **Major:** Detachment of the cuff membrane from the mucosa around the laryngeal inlet with visible air tract present in the fold that potentially may compromise the airway seal (e.g. extends into the piriform sinus).

Size of cuff with regard to the laryngeal inlet:

a. **Too big:** Cuff orifice and/or cuff cup large enough to
   - result in poor cuff alignment around the laryngeal inlet with or without major cuff folding.
     OR
   - compress laterally the laryngeal inlet
b. **Too small:** Cuff orifice of insufficient size to accommodate the laryngeal inlet.
c. **Correct:** none of above

Depth of cuff:

a. **Correct:** apposed to the laryngeal inlet.
b. **Too shallow:** The cuff orifice displaced cephalad in relation to the laryngeal inlet.
c. **Too deep:** The cuff orifice displaced caudad in relation to the laryngeal inlet and/or the cuff membrane is folded and depresses the upper part of the laryngeal inlet.

7.2.8. Data Regarding Complications

The following complications were specifically monitored: arterial oxygen desaturation; lip damage; blood staining on mask removal; and laryngospasm [103, 104]. We evaluated the incidence and severity of throat pain, dysphonia and dysphagia in the recovery room (on arrival and discharge) as well as on the first and third postoperative day using a 10-point verbal rating scale (VRS).

7.2.9. Sample Size

The fibreoptic examinations were performed following written patient consent as part of two studies approved by the Galway University Hospitals Research Ethics Committee [53, 126]. As this was a descriptive study, rather than one testing specific hypotheses, no separate sample size calculations were performed. Enrolment was limited by procedure duration and by availability of operator and fibreoptic/video-recording equipment.

7.3. Results

We present data on 20 patients. Fibreoptic examinations were performed on 26 patients. From the final analysis we excluded 6 patients where data were lost or were of insufficient quality due to equipment issues (e.g. issues with signal transmission from Ambu® Scope™ II screen to the video recording equipment).

7.3.1. Patient Demographics

The patient characteristics are displayed in Table 7.3. Our cohort consisted of 20 low-risk patients aged 29 to 76 years. Of them, 15 (75%) were females and 5 (25%) males. The patients did not have a history of prior difficulties with airway management and their airways were deemed favourable.

The case-mix consisted of gynaecological (hysteroscopy, D&C, laparoscopy), general surgical (hernia repair, breast surgery, wound debridement) and urological (cystoscopy and removal of stones) procedures.

Data regarding anaesthesia are presented in Table 7.4. The majority of cases lasted less than 1 hour. On average the patients were on controlled ventilation for over 90% of the total anaesthetic time.

Table 7.3. Characteristics of the patients enrolled in the study

Number of patients	20
Age; years	47 (14.4)
Body mass index; $kg.m^{-2}$	28.1 (5.5)
Patient height; cm	170.2 (8.4)
Patient weight; kg	80.9 (15)
ASA physical status	2 (1-2 [1-2])
Airway measurements Thyromental distance; cm Inter-incisor distance; cm	 7.8 (1.5) 4.7 (0.6)
Mallampati classification 1 2 3 4	 13 (65%) 7 (35%) 0 0
Type of surgery Gynaecological General surgery Urology	 14 (70%) 4 (20%) 2 (10%)

Note: Values are reported as mean (SD), median (IQR [range]) or number (proportion).

7.3.2. Baska™ Mask Insertion, Performance and Complications

The Baska™ mask was inserted successfully in 100% of the patients. No patient required more than 2 mask insertion attempts. Optimisation manoeuvres to assist mask placement were required in 14 (70%) patients. Masks used successfully included sizes 4, 5 and 6. Baska™ mask insertion and anaesthetic management data are summarised in Table 7.4. The duration of controlled ventilation exceeded 90% of the anaesthetic time in all but 2 patients.

The mean (SD) airway leak pressure was 38.9 (2.9) cm H_2O and no patient had leak pressure below 30 cm H_2O. Prior to the fibreoptic examination the mean (SD) peak and plateau airway pressures were 17.5 (4.4) and 10 (4.5) cm H_2O respectively, indicating patent airway pathways. The leak fractions under volume controlled ventilation remained stable during testing in four different head positions.

No patients required mask re-positioning or change during the anaesthetic. There were no instances of laryngospasm on emergence. In 4 (20%) patients blood staining was noted on mask removal.

Baska™ mask performance data are summarised in Table 7.5.

Table 7.4. Device insertion and anaesthesia data

Overall insertion success rate	100%
Number of insertion attempts	1 (1-1[1-2])
1	13 (65%)
2	7 (35%)
Size of Baska™ mask inserted successfully:	
4	6 (30%)
5	10 (50%)
6	4 (20%)
Duration: min	
Anaesthesia	49.3 (26.2)
Surgery	40.4 (19.8)
Controlled ventilation	46.1 (26.5)
Airway pressures; cm H_2O	
Peak	17 (14-41 [12-26])
Plateau	8 (6-13 [5-18])

Note: Values are reported as mean (SD), median (IQR [range]) or number (proportion).

Table 7.5. Data regarding Baska™ mask performance and complications

Airway leak pressure; cm H_2O	38.9 (2.9)
Measured mask leak; %	
Supine	4 (3-5 [0-12])
Head rotated	3 (2-6 [1-13])
No pillow	6 (4-9 [0-15])
Head extended	4 (2-7 [0-39])
Patients with audible leak:	
at 0 min	4 (20%)
at 5 min	0%
Peripheral oxygen saturation during insertion attempt	
Lowest value; %	98.9 (0.9)
Patients with SpO_2 < 90%	0%
Need to reposition mask intraoperatively	0%
Laryngospasm	0%
Blood staining	4 (20%)
Lip damage	0%

Note: Values are reported as mean (SD), median (IQR [range]) or number (proportion).

7.3.3. Fibreoptic Evaluation

The findings of the fibreoptic evaluations are summarised in Table 7.6. The assessment criteria used are defined in Table 7.2.

7.3.3.1. Baska™ Mask Alignment with the Laryngeal Inlet

The alignment of the Baska™ mask cuff was around the laryngeal inlet was good or satisfactory in 14 (70%) patients (Figure 7.1). In the remaining 6 (30%) patients in whom the alignment was poor had peak airway pressures between 13 and 26 cm H_2O during positive pressure ventilation. Five of these 6 patients had airway leak pressures between 38 and 40 cm H_2O and in one a value of 30 cm H_2O was recorded.

The majority of fibreoptic examinations were performed under positive pressure ventilation. On at least two recorded video sequences the patients had spontaneous breathing activity, and the alignment of the Baska™ mask cuff around the laryngeal inlet was satisfactory and stable.

In 18 (90%) of the patients the epiglottis was pushed under the Baska™ mask cuff into the cuff orifice (Figure 7.1). This was not considered to result in glottic obstruction. On fibreoptic imaging, one case was deemed to have potential for airway obstruction by virtue of the depressed epiglottis (Figure 7.2) yet the recorded peak airway pressure was normal and the anaesthetic was uneventful. On analysis of the video recording of this patient we were able to demonstrate that the device cuff was not in the midline but in the left (as seen on the screen) piriform fossa.

Table 7.6. Fibreoptic Examination Data

Alignment around laryngeal inlet - good - satisfactory - poor	 4 (20%) 10 (50%) 6 (30%)
Epiglottis pushed under cuff	18 (90%)
Cuff folding: - none - minor - major	 4 (20%) 10 (50%) 6 (30%)
POGO score (%)	94 (22)
Patients with POGO score > 85%	19 (95%)
Cuff size: - correct - too big - too small	 9 (45%) 8 (40%) 3 (15%)
Cuff position: - correct - too deep - too shallow	 8 (40%) 8 (40%) 4 (20%)
Evolution of cuff configuration on repeat fibreoptic examination	1 (5%)
Potential for airway obstruction by cuff and/or epiglottis	3 (15%)
Blood staining during fibreoptic examination	0

Note: Values are reported as number (proportion) or mean (SD).

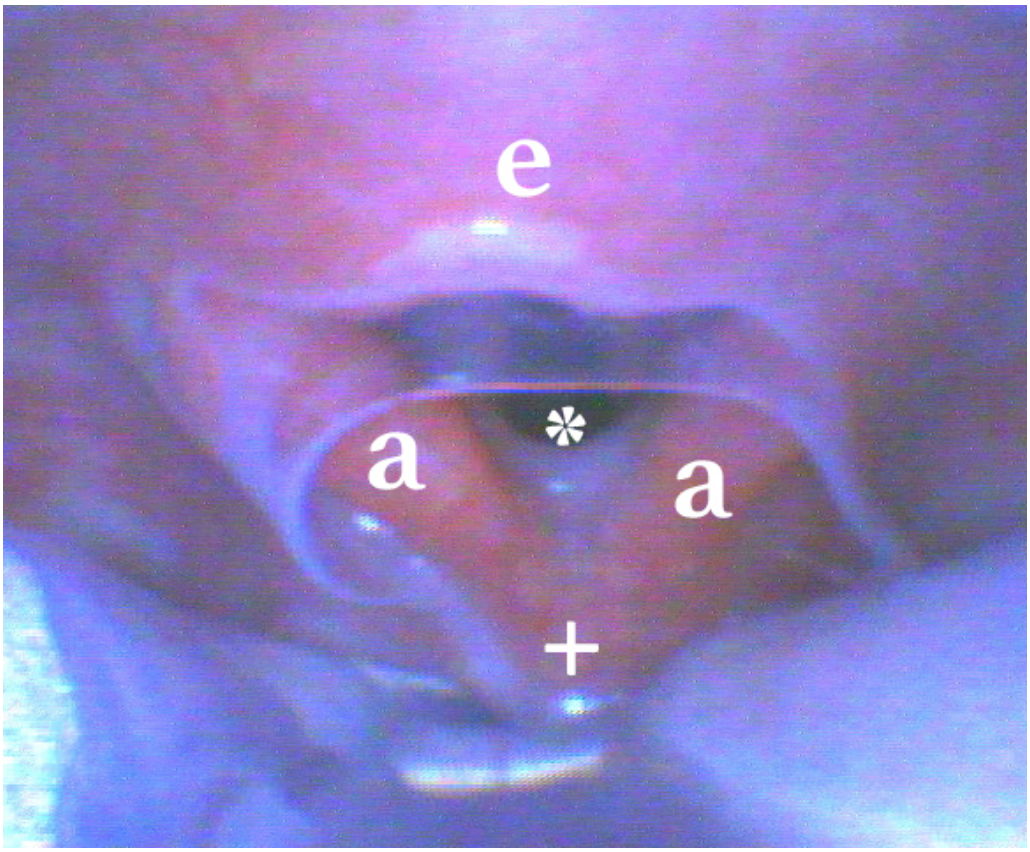

Figure 7.1. An example of good Baska™ mask cuff alignment around the laryngeal inlet.

Note: The cuff membrane is well aligned around the epiglottis (**e**), the aryepiglottic folds (**a**) and the posterior commissure (**+**). It does not obstruct the glottic orifice (*****). Image by V. Alexiev

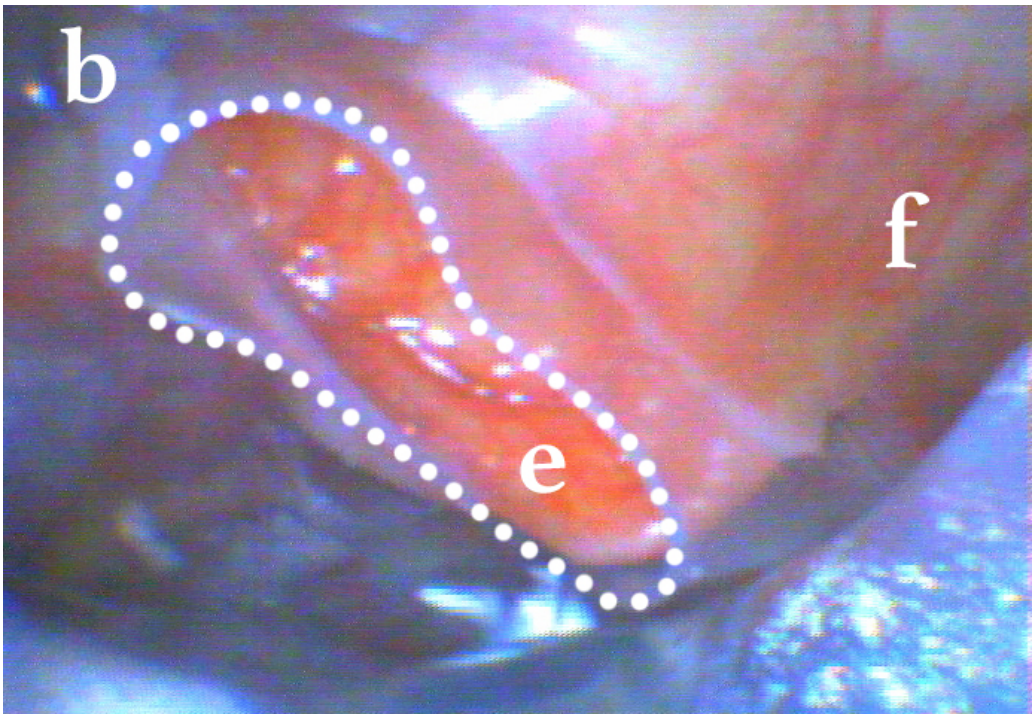

Figure 7.2. Picture demonstrating epiglottis displacement deemed to have a potential to cause airway obstruction.

Note: The epiglottis (**e**) is pushed under the cuff orifice (highlighted with dotted line). The glottic orifice (not seen) is under the epiglottis. The ventilation parameters were not indicative of airway obstruction and positive pressure ventilation was easily accomplished. On dynamic imaging we discovered that the mask was positioned off the midline, in the piriform fossa, with the mask orifice just above the lateral edge of the epiglottis (while this is not obvious on this still image the base (**b**) of the epiglottis is on the left, and its free end (**f**) is on the right). Image by V. Alexiev

7.3.3.2. Baska™ Mask Cuff Folding

Minor cuff folding around the laryngeal inlet (Figure 7.3) was noted in 10 (50%) cases, and major cuff folding with incomplete alignment around the laryngeal inlet (Figure 7.4) was noted in 6 (30%) cases. In these 16 (80%) cases the airway leak pressures were 30 cm H_2O and above, and the airway pressure readings and clinical course indicated patent airways.

7.3.3.3. Baska™ Mask Size

On fibreoptic examination the Baska mask cuff in situ was deemed of correct size in 9 (45%) cases (Figure 7.1). In 8 (40%) cases the cuff was classified as "too big" (Figure 7.5). In 3 (15%) patients the cuff was deemed to be too small (Figure 7.2). The patients where the cuff size was deemed inappropriate did not seem to have worse airway leak pressures or airway patency issues.

7.3.3.4. Baska™ Mask Cuff Position

The cuff was deemed to be pushed too deep (Figures 7.3 and 7.6) in 8 (40%) patients and to be too shallow (Figures 7.4 and 7.7) in 4 (20%).

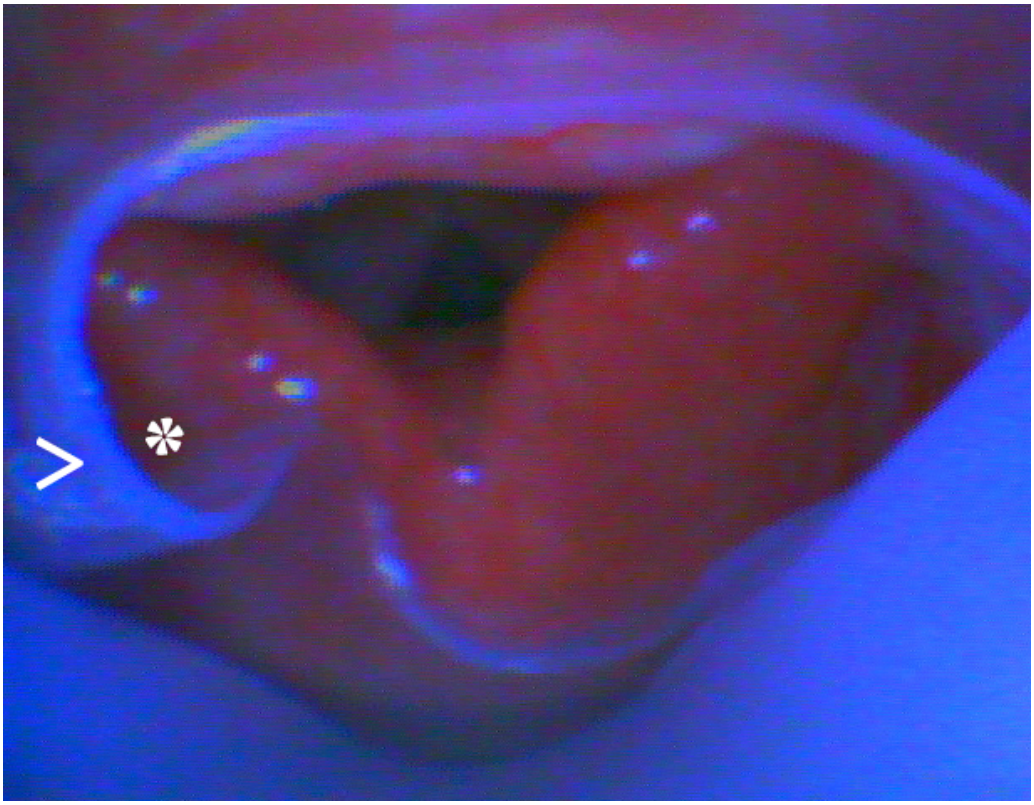

Figure 7.3. Picture showing minor cuff folding.

Note: The mask cuff membrane surrounds the laryngeal inlet. Cuff folding is visible on the left side of the image (**>**). Air tract (*) is seen within the cuff fold. There was no indication of tract extension into the piriform sinus or airway seal compromise on dynamic imaging. Image by V. Alexiev

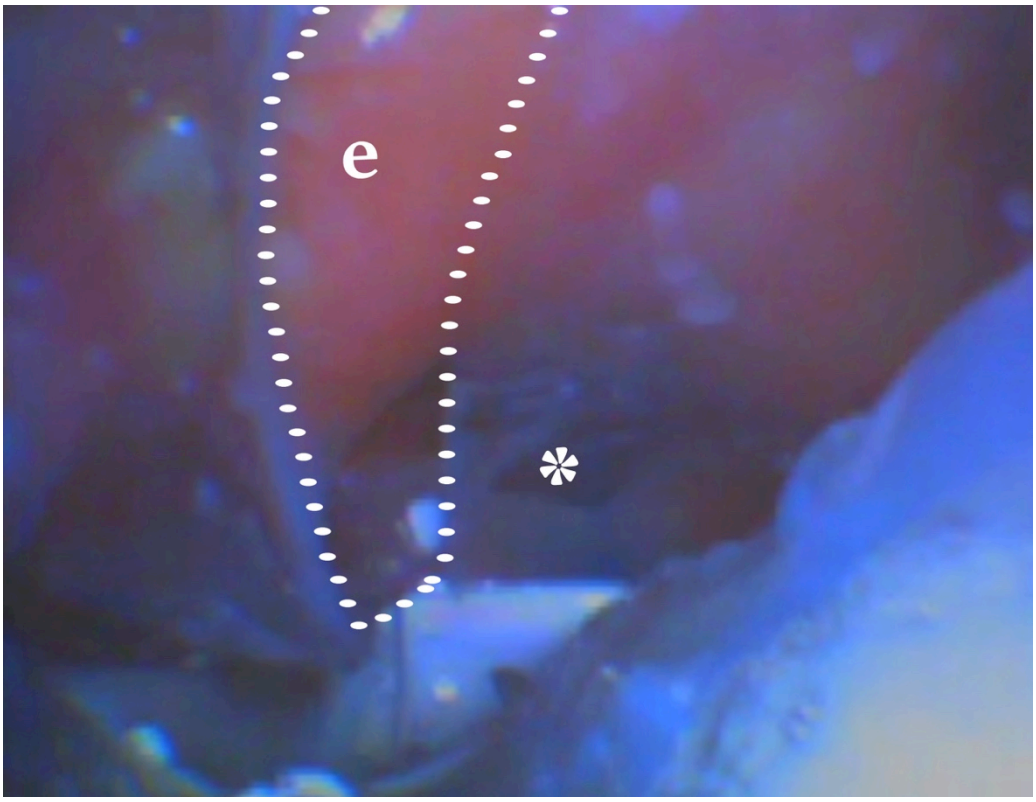

Figure 7.4. Picture demonstrating poor mask cuff alignment around the laryngeal inlet, with major folding.

Note: The epiglottis (**e**) is partially covering the cuff orifice (the cuff orifice is highlighted with dotted line). The glottic orifice (*) can be seen covered by a fold of the cuff membrane. Image by V. Alexiev

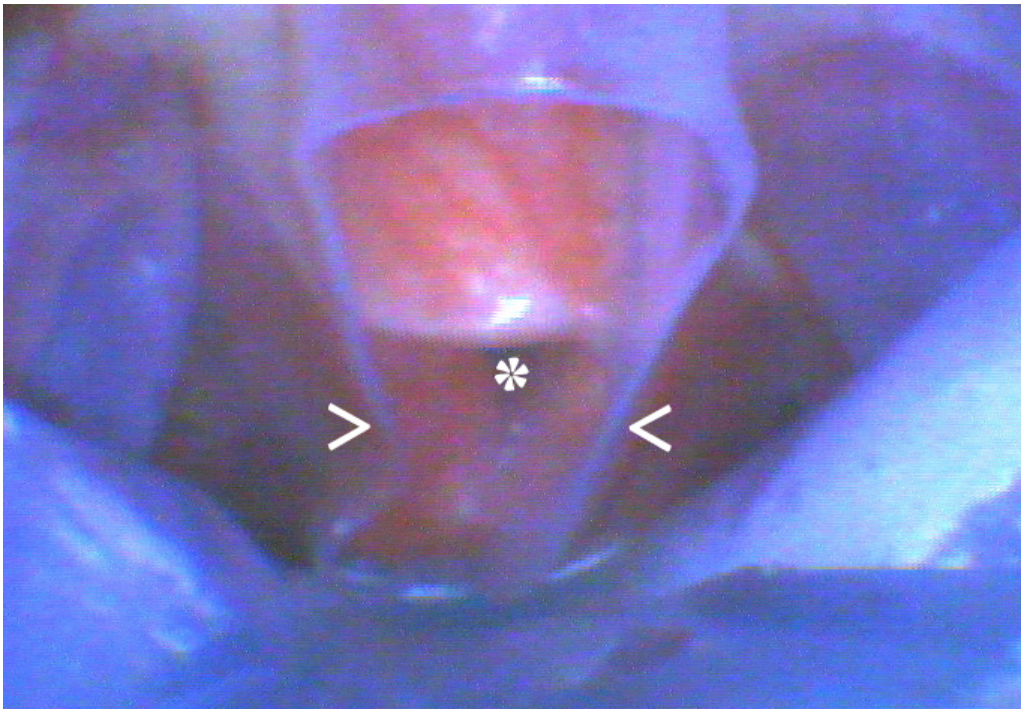

Figure 7.5. Picture demonstrating a Baska™ mask cuff compressing the laryngeal inlet.

Note: The cuff was deemed to be too large, displacing the aryepiglottic folds towards the midline (**<**) and compressing the glottic orifice (*****). Image by V. Alexiev

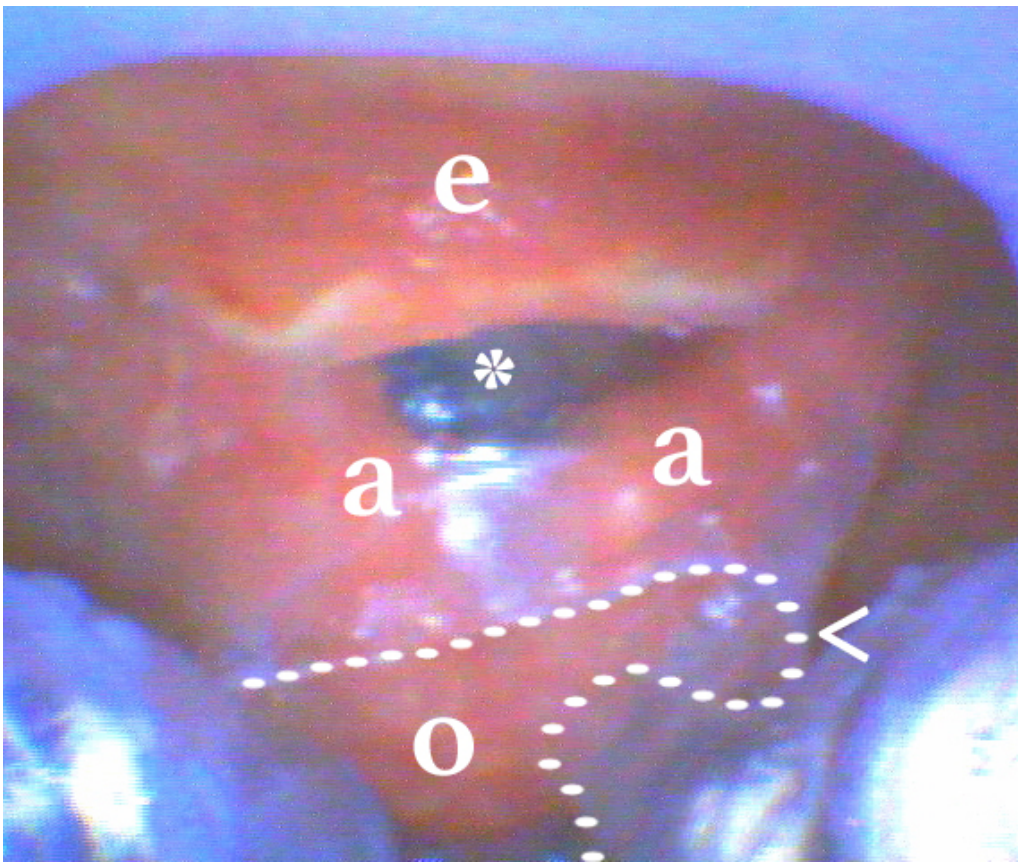

Figure 7.6. Picture illustrating a mask that has been pushed too deep inside the pharynx.

Note: The epiglottis (**e**), the glottic orifice (*****) and the aryepiglottic folds (**a**) are covered by the cuff membrane. The cuff membrane rim is highlighted with a dotted line. The cuff orifice (**o**) is partially caudad to laryngeal inlet. There is cuff folding (**<**) on the right side of the cuff orifice. The cuff orifice appears too small relative to the size of the laryngeal inlet. Image by V. Alexiev

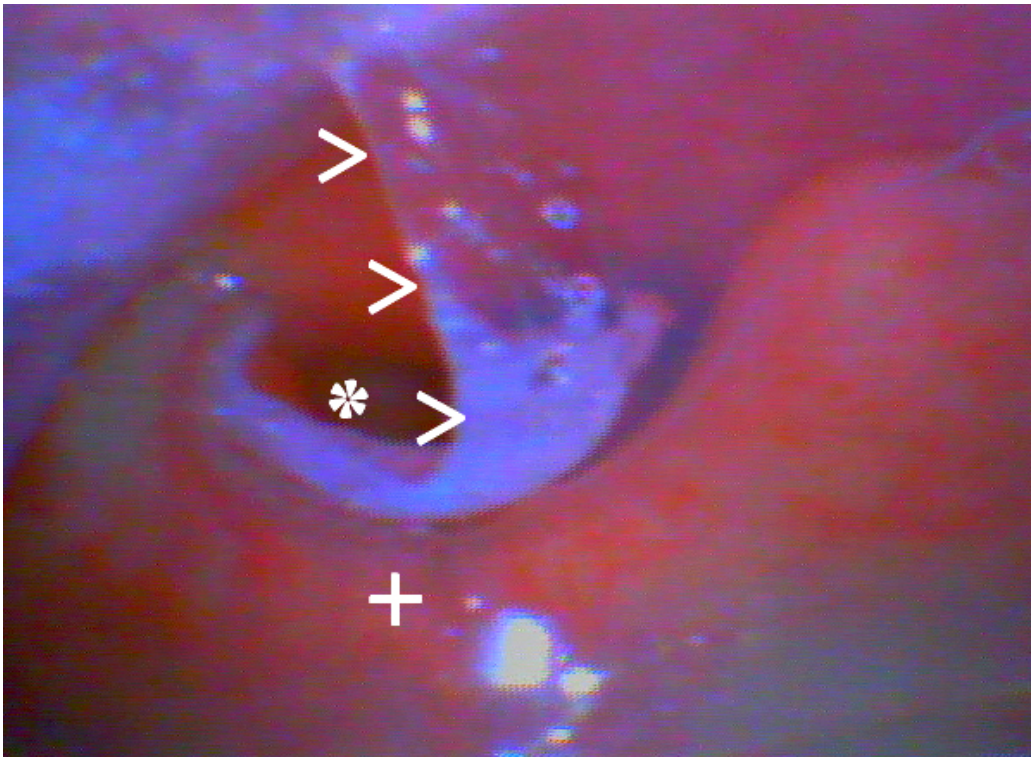

Figure 7.7. Picture illustrating a Baska™ mask placed at insufficient depth.

Note: The laryngeal inlet (*****) is partially covered by the cuff membrane (**>**). The rim of the cuff is above the posterior commissure (**+**) and overall the cuff orifice is partially cephalad to the laryngeal inlet. Image by V. Alexiev

7.3.3.5. Cuff Orifice and Laryngeal Inlet Misalignment

In 7 (35%) patients the Baska™ mask cuff orifice was deemed to be partially displaced relative to the laryngeal inlet (Figures 7.2, 7.4 and 7.7), in two of these the cuff orifice was deemed to be too small (Figure 7.2). This did not have impact on the airway seal or airway pressures. In three of these patients the extent of misalignment was considered to pose a risk of airway obstruction (Figures 7.4 and 7.8a).

7.3.3.6. Intraoperative Baska™ Mask Cuff Configuration changes

In one patient an improvement of the alignment of the Baska™ mask cuff around the laryngeal inlet was observed on repeated fibreoptic examination (Figure 7.8).

7.3.3.7. Blood Staining

Blood staining was not observed on fibreoptic examination in any patient yet blood on the mask cuff was noted on device removal in 4 (20%) patients.

7.3.3.8. Percentage of Glottic Opening (POGO) scores

The POGO score quantifies the extent of visualisation of the glottic opening limited posteriorly by the interarytenoid notch and anteriorly by the anterior commissure [125]. In 18 (90%) patients the score was 100% (full visualisation), in one patient the score was 86% and in one 0% as we could not obtain direct view of the glottic orifice.

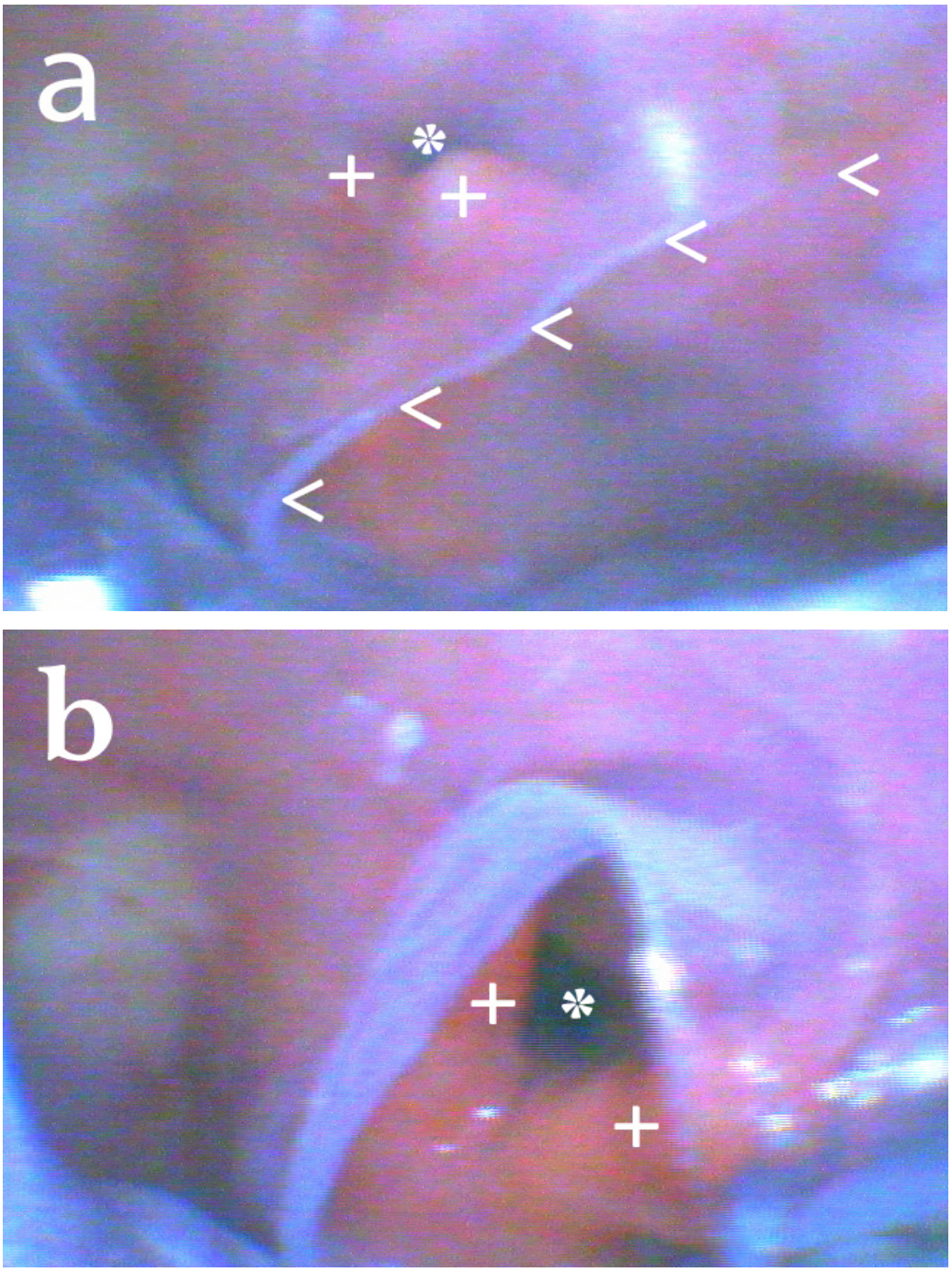

Figure 7.8. Pictures demonstrating the evolution of the Baska™ mask cuff alignment around the laryngeal inlet.

Note: Panel "**a**" demonstrates the glottic orifice (*****) and the aryepiglottic folds (**+**) covered by the cuff membrane (**<**). Panel "**b**" shows evidence of cuff expansion and improved alignment around the laryngeal inlet on subsequent examination of the same patient. Image by V. Alexiev

7.4. Discussion

7.4.1. Patient Characteristics

Our cohort consisted of low-risk adults. In nearly all patients over 90% of the anaesthetic time was under controlled ventilation. Our observations should be interpreted accordingly. The positive pressure exerted by the ventilator might have affected the Baska™ mask configuration by facilitating cuff expansion.

7.4.2. Baska™ Mask Cuff and Laryngeal Inlet

In 70% of our patients the Baska™ mask cuff was well aligned around the laryngeal inlet. This group, as well as the patients deemed to have poor alignment, had satisfactory airway leak pressures and peak pressures during positive pressure ventilation. This suggests that perfect cuff alignment around the laryngeal inlet is not essential for proper cuff function. While not specifically recorded, spontaneous breathing was present in at least two instances of fibreoptic examination. In these patients the cuff was well aligned around the laryngeal outlet.

In the majority of our patients the epiglottis was found to be under the upper part of the Baska™ mask cuff, often protruding into the mask cup (Figure 7.5). Our finding indicates that such a configuration might be the norm with this device. Studies on LMA devices suggest that such configuration is less common [26, 127].

7.4.3. The Baska™ Mask Dual Airway Seal Concept

The Baska™ mask cuff consists of a membrane that can be divided into a peripheral, thicker part and a central thinner part around the cuff orifice that bends inwards into the cuff bowl (Figure 7.9).

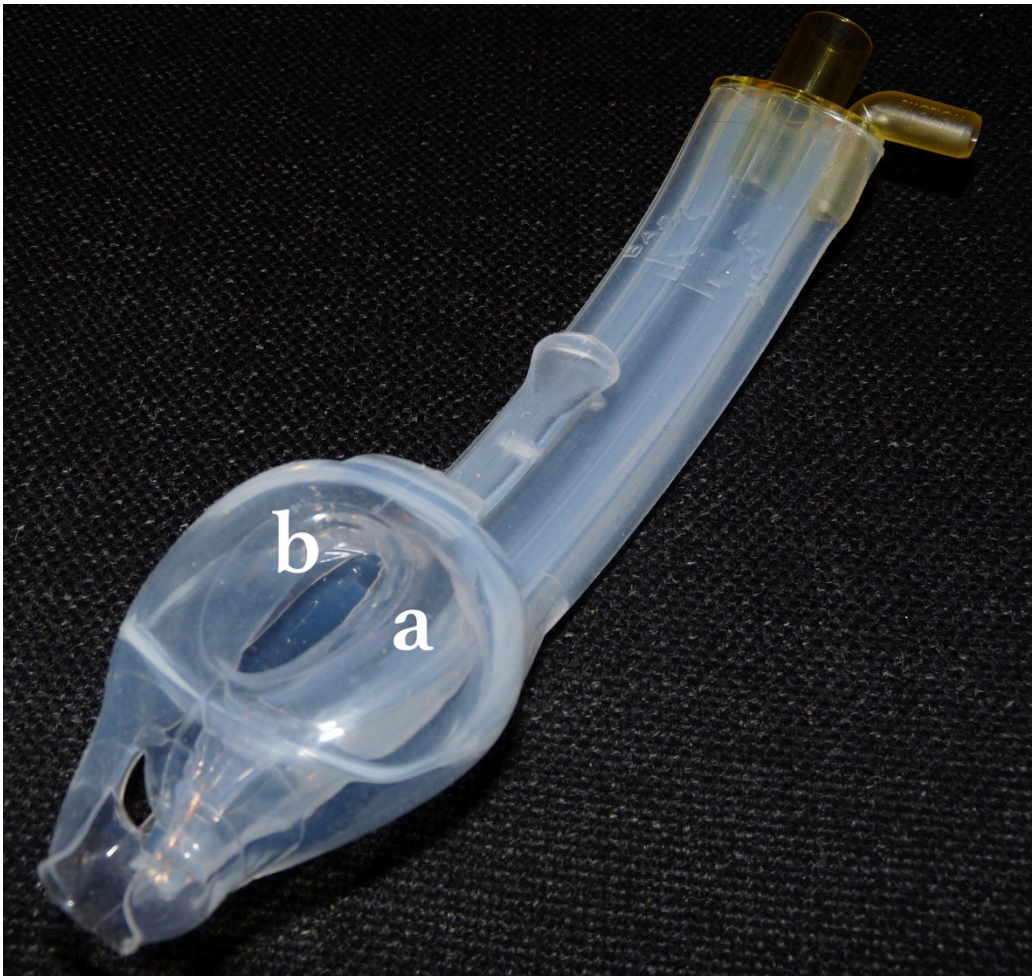

Figure 7.9. Picture of the Baska™ mask illustrating the peripheral thicker part of the cuff membrane (a) and the central thinner part around the cuff orifice, bending inwards into the cuff bowl (b). Image by V. Alexiev

The peripheral part of the cuff membrane provides an airway seal ("pharyngeal" seal) by means of contact with the pharyngeal mucosa near the larynx, similar to the laryngeal mask airway (Figure 7.10) or the i-gel®. In our cohort, the central part of the cuff membrane was well aligned around the laryngeal inlet in the majority of cases, covering the epiglottis and following the contours of the aryepiglottic folds (Figure 7.1). We hypothesize this might provide a second, "laryngeal" airway seal. This combination of two seals might explain the superior airway leak pressures demonstrated by the Baska™ mask [53, 106, 117, 126]. If this concept is correct, the downfolding of the epiglottis under the cuff into the cuff orifice, so it is sealed as part of the laryngeal inlet, might be advantageous, contrary to prior beliefs [26], as long as it does not obstruct the laryngeal inlet.

7.4.4. Baska™ Mask Cuff Folding

As the cuff membrane thickness is less than 1 mm in the central part around the cuff orifice, some folding might be expected when positioned around the laryngeal inlet (Figure 7.3). This was frequently observed in our cohort. Furthermore, in 6 (30%) patients this folding was considered major. Possible explanations for cuff folding (apart from the natural adaptation to the particular patient's anatomy [79]) were that the Baska™ mask size was too big (Figure 7.5), or that the device was inserted too deep (Figure 7.3) or too shallow (Figure 7.4).

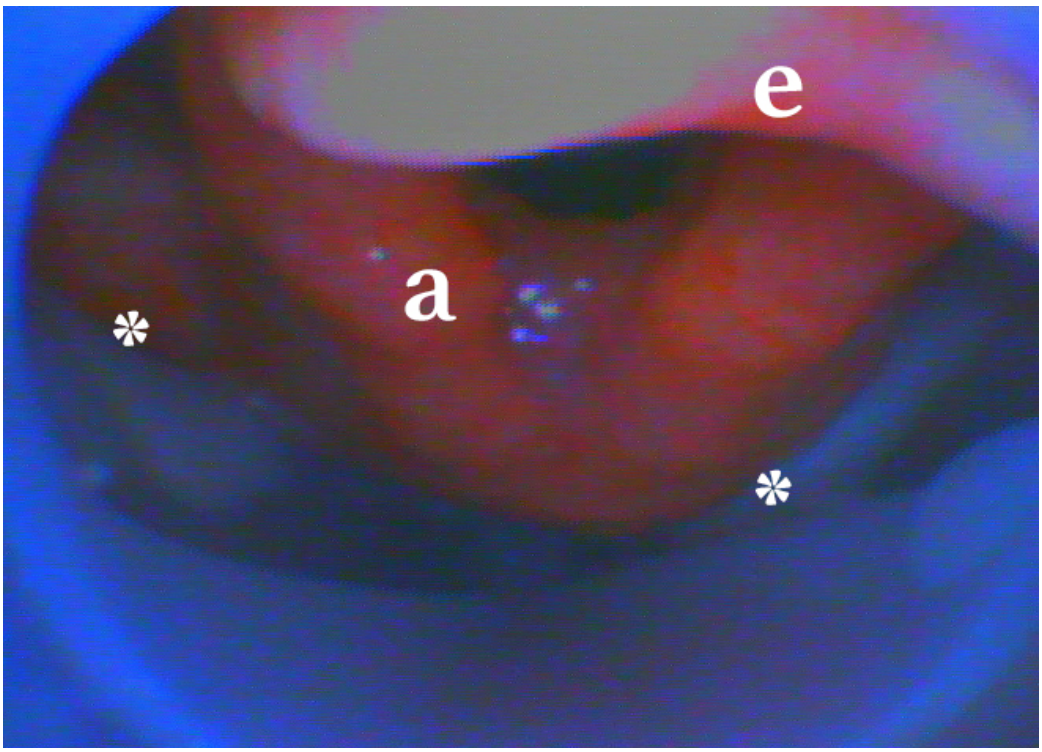

Figure 7.10. Picture of the classic laryngeal mask airway, illustrating the cuff in contact with the pharyngeal mucosa near the laryngeal inlet.

Note: The area of contact between the cLMA cuff and the pharyngeal mucosa is marked with asterisks (*). Please note that the aryepiglottic folds (**a**) are not in contact with the cuff. The epiglottis (**e**) is in the mask bowl. Compare with Figure 7.1. Image by V. Alexiev

7.4.5. Baska™ Mask Insertion

The Baska™ mask cuff orifice is significantly smaller as compared with that of similarly sized SADs [118] (Figure 7.11). Accordingly, optimal alignment of the cuff around the laryngeal inlet will require a level of precision not necessary with other SADs. This assumption is supported by the finding that in a high percentage of our patients additional optimisation manoeuvres (pushing the device further in, rotation or pulling it slightly out) were required during insertion in order to achieve satisfactory mask function [53, 106, 126].

The Baska™ mask cuff was deemed to be positioned too deep or too shallow in 60% of our patients (Figures 7.6 and 7.7). This again points to the potential difficulties in achieving a good cuff position around the laryngeal inlet. The clinical significance of this finding remains unclear, as in all of our patients the quality of the airway seal and the ventilator parameters were satisfactory.

7.4.6. Baska™ Mask Size

The Baska™ mask size was deemed to be too big (Figure 7.5) or too small (Figure 7.2) in 55% of our patients. Again, the clinical significance of this finding remains unclear as in the quality of the airway seal and the ventilator parameters were satisfactory in these patients. Further work is required in defining the optimal sizing strategy of the Baska™ mask [126].

Figure 7.11. Picture demonstrating the small cuff orifice of the Baska™ mask as compared to similarly sized LMA Supreme™ and i-gel®. (Image by V. Alexiev)

7.4.7. Baska™ Mask Cuff Configuration Dynamics

In our previous work we noted that an audible leak was present immediately after Baska™ mask insertion in many patients, yet it disappeared in nearly all by 5 minutes [53, 106, 126]. This notion is suggestive of evolving mask alignment with the laryngeal inlet over time and was supported by findings of sequential fibreoptic exams in at least one patient in our cohort (Figure 7.8). The fact that similarly convincing visual findings were not found in other patients suggests the process likely occurs early after mask placement. The changes in the Baska™ mask cuff configuration could be related to multiple factors (e.g. cuff expansion during positive pressure ventilation, patient muscle tone changes, fibreoptic bronchoscope manipulations etc.).

7.4.8. Baska™ Mask Complications

Fibreoptic examinations were performed only after successful placement and sustained adequate ventilation. Accordingly, we have no visual data on Baska™ mask cuff behaviour in cases where the device was not placed successfully. Interestingly, in 3 (15%) of our patients the mask configuration was deemed to have potential for airway obstruction (Figures 7.2, 7.4 and 7.8a) yet the anaesthetic course was uneventful. The clinical relevance of this finding remains unclear. Payne reported an incidence of partial obstruction with cLMA of 10% [128].

Blood staining was not observed during the fibreoptic examinations in any patient. On emergence from anaesthesia blood staining was present on the mask cuff in 4 patients. Possible explanations for this disparity are that the bleeding occurs later (e.g. on mask removal) and/or in other area (perhaps at the point where the mask drainage orifice enters the upper oesophagus).

In 11 (55%) patients the fibreoptic examination was suggestive the Baska™ mask was too big and/or was pushed too deep. There was no indication of increased incidence of patient discomfort (throat pain, dysphonia or dysphagia) in this group.

7.4.9. POGO Scores and Visualisation of the Glottic Inlet

Levitan et al. proposed the POGO score as a way of quantifying the extent of visualisation of the glottic opening during laryngoscopy [125]. Previous SAD studies have demonstrated poor correlation between fibreoptic assessment of device position and performance [129-131]. Nevertheless fibreoptic guidance may be of value when intubation is attempted via SAD airway lumen [132]. Standardised scope position at the end of the airway channel was proposed when reporting the findings of fibreoptic studies of SADs [51, 133, 134]. During fibreoptic intubation an improved view of the glottic inlet may be obtained when the scope is advanced further. Accordingly, we calculated POGO scores on the best views obtained in each patient rather than views obtained in a pre-determined scope position.

In 95% of our patients we were able to obtain good view of the glottic inlet, which compares well with data published for i-gel® and LMA ProSeal™ [88, 135, 136]. Only one patient in our cohort had a score below 85%. On this occasion we could visualise the glottic inlet via the transparent cuff membrane covering it, yet the score assigned was 0% as we did not obtain unobstructed view.

7.4.10. Limitations

Our sample size was small. The fibreoptic evaluation was performed following a leak test and airway stability manoeuvres were carried out thus the mask position and/or configuration may have changed. The fibreoptic examination per se carries a potential for affecting the mask depth and cuff configuration. The examinations were performed in patients where cuff placement and ventilation were successful, thus our findings do not give insight into situations where the Baska™ mask failed. Our sample had gender imbalance (75% females and 25% males).

7.5. Conclusions

We found that the Baska™ mask cuff has two potential airway sealing zones (one in contact with the pharyngeal mucosa similar to other SADs and one encircling the laryngeal inlet) and propose the concept of a dual airway seal. This dual airway seal may explain the superior airway leak pressures demonstrated by the Baska™ mask. The cuff orifice of this device is smaller than that of similarly sized SADs and accordingly more precise alignment of the cuff orifice around the laryngeal inlet is likely required. This may explain the challenges we observed during device insertion.

We found that the Baska™ mask cuff was aligned well around the laryngeal inlet in 70% of our patients. The airway leak pressures and peak airway pressures during positive pressure ventilation in the remaining 30% patients were not indicative of worse airway seal or of airway obstruction. In 55% of our cases the cuff size was deemed to be too big or too small, yet again this did not seem to have impact on the device performance. We demonstrated that the Baska™ mask alignment around the laryngeal inlet evolves over time. Finally, in 15% of patients the visual findings were suggestive of potential for airway obstruction yet these cases had an uneventful anaesthetic.

8. Discussion

8.1. Supraglottic Airway Devices – have we reached perfection?

Given the multitude of currently available SADs one might question the need for yet another one. With short learning curves [137, 138], insertion success rates approaching 100%, reliable performance and low complication rates[51, 86-88] this question seems justified. The answer is "Yes", there is a need for a better SAD. There is a potential for improvement in the airway seal quality, device drainage system, type and rate of complications, ease of use as well as the device learning curves.

The endotracheal intubation remains the gold standard in securing the airway [24], despite the fact that it is more difficult to master and has potential to result in major morbidity [24, 31, 41, 45, 46, 138, 139]. The ETT offers superior airway seal and protection from aspiration as compared with the SADs [24, 27, 34]. Endotracheal intubation is the standard of care for many types of surgery (e.g. in patients at increased risk of gastric aspiration), in ICU patients, and is desirable in other scenarios [140-142]. In situations where there is no qualified operator available to place an ETT or placement attempts fail, the supraglottic airway devices are an established alternative [143, 144]. A novel SAD with improved airway seal and gastric content drainage system might be a step forward and, in addition, may make SAD use more acceptable where such use is currently contentious [27-30].

The currently available SADs have the potential to cause morbidity related to the pressure exerted by the device cuff on the surrounding tissues [65-67]. The apparently low incidence of these complications translates into large numbers of actual patients given the widespread use of SADs [43]. A device with a novel approach to the cuff design might address this problem.

The proper use of airway devices requires skills acquired over time [31, 41, 47, 48]. A device with good performance in the hands of inexperienced operators will offer obvious advantages.

8.2. The Baska Mask – a Step Forward?

The novel features of the Baska™ mask offer potential advantages. The device cuff is made from a soft non-inflatable membrane, shaped to fit closely around the laryngeal inlet, aimed at minimising the pressure on the pharyngeal tissues and yet providing improved airway seal. The mask incorporates a novel pharyngeal drainage system aimed at reducing the risk of gastric contents aspiration. The device's stump design is aimed at increasing the ease of device insertion.

8.3. The Baska Mask – Exploring its Clinical Utility

We planned a series of studies to accumulate information regarding the performance and safety profile of this novel airway device. We performed 3 pilot studies on adult female, male and paediatric patients as well as a randomised controlled trial comparing the Baska™ mask with a single use cLMA. In addition we performed fibreoptic examinations evaluating the behaviour of the Baska™ mask cuff in situ in anaesthetised patients.

8.4. Overall Findings

The Baska™ mask demonstrated an airway seal superior to that reported for other SADs, comparable overall insertion success rates yet lower first insertion attempt success rates [51, 86-88]. In direct comparison with the cLMA, the Baska™ mask provided superior airway seal, comparable overall success rates yet proved to be more difficult to use as demonstrated by longer insertion duration times, more insertion attempts, higher device difficulty scores and more optimisation manoeuvres during insertion [53].

8.5. Specific Findings

8.5.1. Airway Seal

The Baska™ mask demonstrated airway leak pressures consistent with airway seal superior to that of other SADs [51, 86-88]. Our observations are in line with the work of van Zundert et al. and Lopez et al. [117, 118]. The pre-determined maximum airway pressure allowed during leak testing was reached in a significant number of our patients and we observed a learning effect in some of our studies, thus our results likely underestimate the true device leak pressure.

The audible leak observed in many patients immediately after mask placement disappeared in 5 minutes in the majority of them, suggesting that the airway seal improves over time. This finding may be related to mask cuff expansion during positive pressure ventilation and correlates with the sequential fibreoptic examination findings in at least one of our patients.

Based on our fibreoptic findings we hypothesize that the observed superior airway seal of the Baska™ mask is related to the extensive contact area between the device cuff and the patient's mucosa. In addition to covering the pharyngeal mucosa near the larynx (similarly to other SADs) the Baska™ mask cuff membrane covered the epiglottis and the area around the laryngeal inlet. Based on these findings we propose the concept of dual airway seal (Section 7.4.3).

8.5.2. Baska™ Mask Insertion Success Rates

In female patients the overall insertion success rates for the Baska™ mask were comparable with those for the cLMA yet the first-time insertion success rates were lower, insertion times longer and the device difficulty scores less favourable. While this might indicate the Baska™ mask is more difficult to use, contributing factors might be the lesser experience the

operators had with the Baska mask as compared with the cLMA, as well as the fact that the optimal device sizing strategy for the Baska mask remains to be confirmed [82, 88]. Other investigators report overall insertion success rates comparable with our observations yet slightly better first-time insertion success rates [117, 118].

Apart from the worse overall insertion success rate our findings in male patients were comparable to those in females. A learning effect was observed in this study thus our findings need to be interpreted with caution.

Compared with other SADs the cuff orifice of the Baska™ mask is relatively small, thus more precise alignment with the laryngeal inlet might be required. This notion is supported by the fact that optimisation manoeuvres were required during device insertion in high proportion of our patients. The latter observation is supported by similar findings in the work of Lopez et al. [118].

8.5.3. Baska™ Mask Size

Baska™ masks of larger size were used in heavier, respectively taller patients. Our results in adults indicate that size 4 might be a good first choice in average females, size 5 in taller and/or heavier females, size 5 or 6 in average males and size 6 in taller and/or heavier males.

8.5.4. Device Safety Profile

The incidence of perioperative complications (e.g. laryngospasm, desaturation, device failure, teeth damage etc.) as well as the postoperative patient comfort indices were comparable between Baska™ mask and the cLMA in female patients. Of note the incidence of blood staining on mask removal was higher but this did not seem to translate to an increased incidence of clinically relevant complaints up to 3 days postoperatively. We noted higher intraoperative failure rates in male patients and a higher incidence of laryngospasm in the paediatric population yet these results

have to be interpreted with caution given the small sample size of the relevant studies and the high proportion of ENT patients in our paediatric cohort. In our paediatric study we specifically monitored the patients for gastric distension. No such events were observed.

8.5.5. Learning Curve

In our initial pilot study in female patients we observed a short learning curve, with sustained improvement in insertion times, success rates and airway leak pressures after 10 device placements. Separate clinical trials are required to verify the validity of this finding as this study involved one operator.

8.6. Limitations

Our studies have limitations and accordingly the results have to be interpreted with caution. All our patients were deemed to have low-risk airway thus the performance of the Baska™ mask in patients with difficult airway was not examined. Further studies are required to evaluate the performance of the Baska™ mask in spontaneously breathing patients as our patients underwent controlled ventilation over 80% of the anaesthetic time.

On commencement of our project no independent information was available as regarding the performance and the safety of the Baska™ mask. Extra caution was exercised and this may have affected our results. The pilot studies on female, male and paediatric patients included small number of patients and in addition a learning effect was present. The operators placing SADs in the randomised controlled trial on female patients had more experience with the cLMA than with the Baska™ mask.

The device difficulty scores as well as the patient comfort scores are subjective. The anaesthetists placing the devices could not be blinded thus

operator bias was possible. Furthermore in the pilot studies the patients were not blinded and patient bias may have affected our results.

8.7. Future Research Suggestions

As with the results of any single-centre trial our findings need to be verified by independent investigators in adequately powered randomised controlled trials. Future work is needed to refine the device sizing guidelines as well as to accumulate information regarding the device safety profile, in particular in children. Learning curve studies are required to verify our initial observations on operator skill evolution. An assessment of the novel Baska™ mask drainage system would seem another area for future research.

9. Conclusions

9.1. Airway Seal

The Baska™ mask demonstrated an airway seal superior to the currently available supraglottic first and second generation SADs. Furthermore our findings are likely to underestimate the quality of the seal due to the safety limits we set on the tests utilised.

9.2. Device Insertion

The Baska™ mask appears to be more difficult to insert as compared with the cLMA. This is reflected by the longer insertion times, lower first time insertion success rates, higher device difficulty scores and higher requirement for additional optimisation manoeuvres during the device insertion. The need for sufficient alignment of the small cuff orifice with the laryngeal inlet is likely to contribute to these difficulties as demonstrated by our fibreoptic examination findings.

The overall Baska™ mask insertion success rates in adult female patients were comparable with those for other SADs. Our studies in male and paediatric patients do not allow us to draw reliable conclusions.

9.3. Device Sizing

Baska™ masks of larger size were used in the heavier, resp. taller patients. Our results in adults indicate that size 4 might be a good first choice in average females, size 5 in taller and/or heavier females, size 5 or 6 in average males and size 6 in taller and/or heavier males. Device sizing is complex and remains to be elucidated.

9.4. Baska Mask Safety Profile

The Baska™ mask demonstrated a reasonable safety profile in adult patients. We observed a relatively high incidence of blood staining on mask removal but this did not translate to an increased incidence of patient discomfort or other complications.

In our small sample of paediatric patients we observed an increased incidence of laryngospasm. The significance of this finding is unclear as many of these patients underwent ENT procedures.

9.5. Learning Effect

Our initial studies demonstrated a sustained improvement in the quality of the airway seal and in the duration of successful insertion attempts for an operator with less than 20 device insertions, suggestive of a short learning curve. At this stage it is difficult to separate the learning effect from device sizing and future studies are needed to explore this area.

9.6. Limitations of Findings

Further studies are required in order to explore the clinical utility of the Baska™ mask. The results of our randomised controlled trial comparing the Baska™ mask vs. cLMA in females should be verified by independent investigators. The results of our pilot studies in adult male and paediatric patients may be used in the design of adequately powered randomised controlled trials.

9.7. The Baska Mask - Clinical Utility

Our results clearly demonstrated that the Baska™ mask offers a superior airway seal. This might offer advantages in particular situations (e.g. laparoscopic surgery, obese patients etc.). While the overall insertion success rates were reassuring the device appears to be more difficult to insert as compared with other SADs. Optimisation of the device sizing guidelines has the potential to reduce the insertion difficulties.

10. Publications, Posters and Presentations Arising from Project

Publications

Alexiev, V., Salim, A., Kevin, L.G., Laffey J.G., *An observational study of the Baska mask: a novel supraglottic airway.* Anaesthesia. 2012 Jun; 67(6); p.640-645

Alexiev, V., Ochana, A., Abdelrahman, D., Coyne, J., McDonnell, J.G., O'Toole, D.P., Neligan, P., Laffey, J.G., *Comparison of the Baska mask with the single-use laryngeal mask airway in low-risk female patients undergoing ambulatory surgery.* Anaesthesia. 2013 Oct; 68(10); p.1026-32

Alexiev, V., Coyne, J., Salim, A., Laffey, J. G., *Initial experience with the Baska mask, a novel supraglottic airway device, in female patients undergoing gynaecologic laparoscopic surgery.* Eur J Anaesth. 2012 Jun; 29 (Sup.50), p.229

Alexiev, V., Ochana, A., Quinn, A., Foto, T., McDonnell, J.G., Laffey, J.G., *Selection of optimum Baska mask size in male patients, an initial study.* Irish J Med Sci. 2014; 183(Sup.1); p.S50

Presentations:

V. Alexiev, A. Ochana, M. Scully, J.G. Laffey. A pilot randomised controlled trial of the Baska Mask versus single use LMA device in low-risk female patients. Irish Congress of Anaesthesia 2012, Dublin, Ireland (presented by V. Alexiev. A pilot RCT that informed the design of the RCT presented in chapter 4). Awarded the ICA 2012 Research Medal.

V. Alexiev, A. Ochana, J.G. Laffey. Baska mask – complex of clinical studies. Winterforum 2012, Annual meeting of SSAIM, Strbske Pleso, Slovakia (Presented by V. Alexiev)

V. Alexiev, A. Ochana, D. Abdelrahman, J. Coyne, J.G. McDonnell, D.P.O'Toole, P. Neligan, J.G. Laffey, Comparison of the Baska mask to the single use laryngeal mask airway in low risk female patients undergoing ambulatory surgery. Irish Congress of Anaesthesia 2013, Dublin, Ireland (Presented by D. Abdelrahman). Awarded 2nd place in the Free Paper Presentation contest.

A. Quinn, V. Alexiev, A. Ochana, T. Foto, J.G. McDonnell, J.G. Laffey, Determination of the optimal approach to sizing Baska mask in male patients. Silvester O'Halloran Meeting 2014, Limerick, Ireland (Presented by A. Ochana).

Posters:

V. Alexiev, A. Salim, J. Kelliher, J.G. Laffey, Evaluation of the Baska mask – a new supraglottic airway device, in female patients. Western Anaesthesia Symposium 2012, Galway, Ireland, Awarded the Western Anaesthesia Poster Prize.

V. Alexiev, J. Coyne, A. Salim, J. G. Laffey, Initial experience with the Baska mask, a novel supraglottic airway device, in female patients undergoing gynaecologic laparoscopic surgery. European Society of Anaesthesiology Annual Congress Euroanaesthesia 2012, Paris, France.

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