Journal of Anesthesia & Clinical Research

Almeida et al., J Anesth Clin Res 2016, 7:7
DOI: 10.4172/2155-6148.1000647

Review Article Open Access

Supraglottic Airway Devices: A Review in a New Era of Airway Management

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Received date: May 25, 2016; **Accepted date:** July 14, 2016; **Published date:** July 22, 2016

Abstract

'Supraglottic Airway Devices' refers to a broad set of medical devices capable of acting as a passageway for ventilation, oxygenation and administration of anaesthetic gases. Their adoption has increased gradually over the last decades, having become a fundamental tool in modern anaesthesiology. Brain's 'Laryngeal Mask Airway', introduced in 1983, marked the beginning of a revolution as a new method for airway management, ultimately replacing tracheal intubation as the most used. Initially targeted for simple procedures, supraglottic airway devices (SADs) have been gaining new indications, as many advanced models were introduced with specific designs for better ventilatory performance and higher patient safety. SADs also prove to be useful in critical scenarios both in emergencies, as rescue airways in difficult intubation. Their higher ease and speed of insertion, lower autonomic impact and less post-operative discomfort for the patient are seen as some of the best advantages when compared to the endotracheal tube (ET), but studies with some SADs have shown lower seal pressures and higher incidence of gastric insufflation. There is still not enough evidence to prove that the newer SADs can provide the same level of safety against pulmonary aspiration as the ET. Main advantages in relation to the facemask are easier placement, more reliable ventilation and hands-free operation. Several SADs have features better suited for some scenarios, which has led to a substantial amount of devices available at the same time, being the anaesthetist the responsible for its selection. This demands the knowledge of their specificities and since new devices are always being introduced, continuous learning is paramount. Sometimes the newest devices become available before any evidence is published on them. Attempts at devising a useful classification system have not been completely successful with several different taxonomies proposed but still no agreement among the experts.

Keywords: Supraglottic airway devices; Extraglottic airway devices; Laryngeal mask; Airway management; ventilation; Respiratory failure; Review

Introduction

Supraglottic Airway Devices (SADs) comprise a vast group of tools designed to provide a means for ventilation, oxygenation and administration of anaesthetic gases during situations of respiratory arrest or in a patient who is submitted to a surgical procedure under general anaesthesia. They are used as an alternative to the traditional methods of airway management: the face mask (FM) and the endotracheal tube (ET). This is a field that has witnessed rapid growth lately, becoming central to everyday anaesthetic practice, which warrants continued learning by practitioners (anaesthetists) in order to provide the safest care to their patients.

Some authors refer to these as extraglottic [1,2], periglottic [3] or supralaryngeal [4] airways, but the term 'supraglottic airways' is the most widely used in the literature [5-11]. Although the different words may have distinctive meanings, in this context they all indicate the same group of devices, defined as those which are used for temporary management of the airway, being inserted via the mouth and which do not penetrate the larynx [12].

This review was performed in order to assess some of the most important SADs that have been developed to date, to describe their features and design specificities, highlighting the main advantages and shortcomings in comparison to the FM and ET.

For a proper understanding of the solutions required of and given by this group of medical devices, a brief overview of the history that lead to their invention and adoption in clinical practice is provided.

Another objective of this review is to discuss and analyse the several classification systems that have been proposed to organize the different SADs available.

The bibliography used in this review was gathered from the electronic databases PubMed and Embase between November and December 2015, and the searches were conducted by the first author. The keywords supraglottic airways, extraglottic airways, laryngeal mask airway, airway management, respiratory arrest were used. Cross-referencing was performed and all the relevant literature was included. 78 papers were reviewed, including 16 comparative studies and 7 meta-analyses, published between 1983 and 2015.

Historical Perspective

In the beginning of the 20th century, endotracheal intubation was a very complex procedure, with a high failure rate [13]. Awake intubation was difficult due to gag reflex and laryngospasm was far too common, often resulting in death [14]. Trying to come up with a solution for these problems, Leech introduced the Pharyngeal Bulb Gasway (Figure 1) in 1937 [14]. Instead of dipping into the trachea, this device would be stuck in the pharynx by means of an anatomically-shaped, hollow rubber bulb, becoming the first supraglottic airway device (SAD). Despite the advantages of Leech's airway compared to the face mask (FM) or the ET at the time, it was

Citation: Almeida G, Costa AC, Machado HS (2016) Supraglottic Airway Devices: A Review in a New Era of Airway Management. J Anesth Clin Res 7: 647. doi:10.4172/2155-6148.1000647

never very popular [15]. The use of curare as muscle relaxant by Griffith [16] and the refinement of the laryngoscope by Macintosh [17] led to the widespread adoption of tracheal intubation as the Gold standard for airway management in general anaesthesia. Even Leech no longer used his own invention [15].

Figure 1: Pharyngeal bulb gasway.

It took almost 50 years for another supraglottic airway to be designed. Archie Brain reasoned that tracheal intubation was not ideal in terms of gas flow since having a tube-the ET-inside another-the trachea-, resulted in potentially harmful flow turbulence [18]. He devised the Laryngeal Mask Airway (LMA), which formed an end-to-end connection at the glottis. The concept evolved from home-made prototypes built from the Goldman Dental Mask through an iteration of latex models [19]. After studying post-mortem specimens, an elliptical cuff was invented, which would seal around the larynx [18].

It became available in 1988 in the UK and soon thereafter in Australia, the USA and Japan. The first systematic review was published in 1993 where the authors concluded this was a useful method for airway management in low-risk, elective surgeries in adults, and emphasized the ease and speed of insertion and little autonomic impact [20]. From then on, many other SADs have been developed.

Specific Supraglottic Airway Devices (SADs)

Classic laryngeal mask airway (cLMA) (Figure 2)

Despite not being the first SAD, it was the first with significance. Composed of an oval-shaped inflatable cuff designed to seal around the larynx, it also has two elastic bands to avoid the epiglottis obstructing the passage of air. It is reusable up to 40 times after autoclaving. It has stood the test of time and is used worldwide everyday [8]. Compared to the ET, speed and ease of placement of the cLMA both by inexperienced personnel and trained anaesthetists are increased [21], lower concentrations of anaesthetics are necessary and there is less risk of sore throat [20]. However, it presents lower seal pressures and higher incidence of gastric insufflation [22]. In a survey of cLMA usage in more than 10 thousand patients, it had to be abandoned in favour of an ET in 0.2% [23].

Figure 2: Classic LMA.

LMA unique (Figure 3)

This single-use version of the cLMA was developed after some studies showed protein deposits in cLMAs after autoclaving, leading to concerns of infectious disease, namely prion diseases [24,25]. As expected given it follows the same design as the cLMA, some studies show similar clinical performance [26,27]. A study with more than 15 thousand patients reported a failure rate of 1.1% [28]. Mean oropharyngeal seal pressures range from 17 to 22 cm H_2O [29,30].

Figure 3: LMA unique.

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LMA flexible (Figure 4)

This SAD combines the mask and cuff of the cLMA with a narrow, long and wire-reinforced tube that is flexible. Useful for face and neck surgery providing little risk of airway displacement [31,32].

Figure 4: Flexible LMA.

Intubating LMA (Fastrach) (Figure 5)

Easier to introduce than an ET, this allows for subsequent blind intubation with an ET up to size 8 through itself [33]. It can also be used for ventilation, just like the other SADs. Overall success rate of intubation through this device is around 96% [34-36].

Figure 5: Intubating LMA (Fastrach).

LMA proseal (PLMA) (Figure 6)

This SAD improves upon the design of the cLMA, with better airway seal, having a second, posterior cuff, allowing for a higher oropharyngeal seal pressure of 27 cm H_2O [37]. It was also the first to allow access to the gastrointestinal tract, by means of an oesophageal drain tube. These allowed for better performance and safety [38], reducing risk of aspiration and helping to assess correct placement [39] by inserting a gastric tube one can find the location of the tip of the device. The airway and drain tubes are joined into a rigid structure such as to avoid obstruction in case the patient clenches their teeth.

Figure 6: LMA ProSeal.

LMA supreme (SLMA) (Figure 7)

This is an evolution of the PLMA, with a reinforced cuff preventing folding, narrower curve allowing easier insertion and more stable placement, and it is a single-use device. Several studies have shown non-inferiority compared to the PLMA [40] and superior performance compared to the cLMA [5].

Figure 7: LMA Supreme.

Combitube (Figure 8)

Combining the features of an ET and a gastric tube, this is a single-use, double-lumen tube with two cuffs: a proximal large cuff, which fits the base of the tongue; and another distal, smaller cuff. It was designed to be introduced blindly, such that the tip may go into the oesophagus (more common) or into the trachea (rarely). In case, identifying the situation and connecting the ventilation circuit to the appropriate tube, ventilation can be achieved. The use of the Combitube is not recommended for general anaesthetic procedures [41], being limited to emergency situations, especially out-of-hospital [42].

Figure 8: Combitube.

King laryngeal tube (LT) and king laryngeal tube suction II (LTS-II) (Figure 9)

The LT is composed of a simple airway tube with an oropharyngeal and an oesophageal cuff. There is an opening between the two cuffs, allowing for the passage of gas into the larynx. The LTS-II has a second lumen, which opens into the oesophagus beyond the distal cuff. Like the Combitube, its use is recommended only for emergencies or failure to intubate and ventilate [43,44].

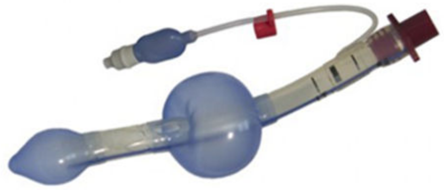

Figure 9: King LT.

Cobra perilaryngeal airway (Figure 10)

Its tip is shaped like the head of a snake and has a grating allowing for ventilation while avoiding obstruction. There is also a large-volume, low-pressure pharyngeal cuff just proximal to the tip. It was found to be similar to the cLMA in terms of ease of insertion but achieved higher sealing pressures [45] and can be used for airway rescue [46].

Figure 10: Cobra perilaryngeal airway.

Streamlined liner of the pharynx airway (SLIPA) (Figure 11)

This is a cuffless device, pre-shaped to sit in the pharynx, with a heel and a hump to fit the soft palate and the base of the tongue, respectively. It has a hollow chamber that can store up to 50 mL of drained gastric fluid. It was designed for short general anaesthetic procedures. It has proven non-inferior to the cLMA and to the PLMA concerning ease and speed of insertion, insertion success rate and oropharyngeal seal pressure [47-49].

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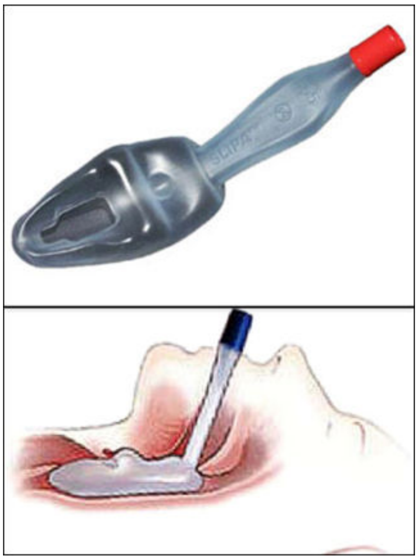

Figure 11: SLIPA.

i-Gel (Figure 12)

This is another pre-shaped cuffless device, made of a gel-like material, which adapts to the anatomic surface after introduction. There is also a channel for insertion of a gastric tube. Several studies have shown superiority in terms of ease and speed of insertion and overall insertion success rate when compared with the cLMA [4,50]. In addition, a meta-analysis comparing it to the PLMA during general anaesthesia found similar oropharyngeal leak pressures and success rate of gastric tube insertion but shorter insertion time and lower incidence of sore throat when using the i-Gel [51].

Figure 12: i-Gel.

Baska mask (Figure 13)

This is one of the latest devices, with a radically different sealing mechanism. It has a non-inflatable cuff, which is continuous with the airway lumen, allowing for expansion with positive pressure ventilation while also avoiding the problems of cuff over-inflation. It achieved better sealing than the cLMA (40 *vs* 22 cm H_2O in a study of 150 patients) but proved more difficult to introduce leading to higher insertion times [29].

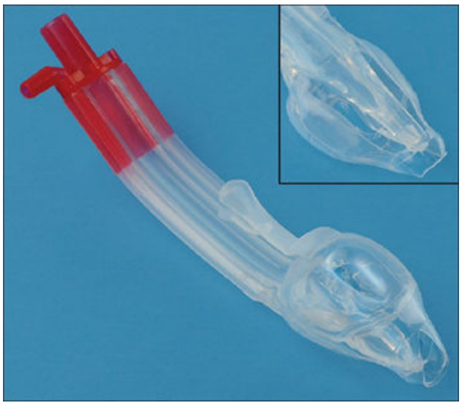

Figure 13: Baska mask.

3gLM (Figure 14)

Like the Baska Mask, it is composed of a non-inflatable cuff, which adapts to the anatomy with positive pressure. It has two gastric tube channels for redundancy [52]. Insertion success rate was 92.5% and the mean oropharyngeal seal pressure was 27 cm H_2O [52].

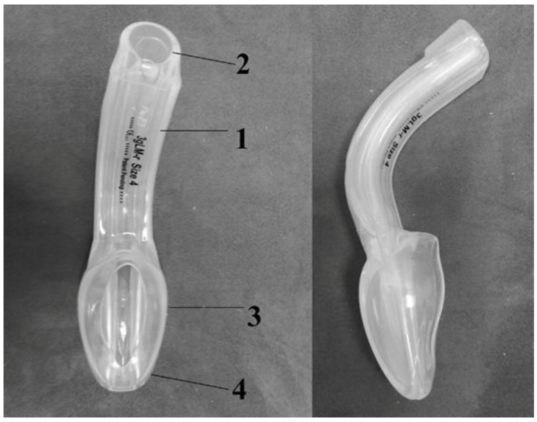

Figure 14: 3gLM.

Table 1 shows a brief summary of the features of these SADs.

Although there are other SADs - most of which are only slightly modified versions of the above, by different manufacturers - these are the most used in everyday practice and also the most studied [1,12,53-57], which also provide a comprehensive picture of the different sealing mechanisms, gastric access and aspiration protection designs. For others, such as the LMA Protector or the Intubating Laryngeal Tube with Drain (iLTS-D) there are no published studies with patients yet. Given the enormous amount of SADs that have been developed to date it would be extremely difficult to describe all of them in this short review. We were unable to find an updated, thorough list of all the SADs available, although Hernandez et al provide a very complete list, only lacking the most recent [12].

SAD	Location of sealing	Sealing mechanism	Aspiration protection	Single-use	Conduit for intubation
cLMA	Perilaryngeal	Inflatable cuff	No specific feature	No	No
LMA Unique	Perilaryngeal	Inflatable cuff	No specific feature	Yes	No
LMA Flexible	Perilaryngeal	Inflatable cuff	No specific feature	Yes	No
Intubating LMA	Perilaryngeal	Inflatable cuff	No specific feature	Yes	Yes
LMA ProSeal	Perilaryngeal	Inflatable cuff	Drainage channel	No	No
LMA Supreme	Perilaryngeal	Inflatable cuff	Drainage channel	Yes	No
Combitube	Base-of-tongue	Inflatable cuff	Drainage channel + Esophageal cuff	Yes	No
King LT	Base-of-tongue	Inflatable cuff	Esophageal cuff	Yes	No
King LTS-II	Base-of-tongue	Inflatable cuff	Drainage channel + Esophageal cuff	Yes	No
CobraPLA	Perilaryngeal	Inflatable cuff	No specific feature	Yes	Yes
SLIPA	Base-of-tongue	Pre-shaped	Storage chamber	Yes	No
i-Gel	Perilaryngeal	Pre-shaped	Drainage channel	Yes	Yes
Baska Mask	Perilaryngeal	Self-energizing	Drainage channel	Yes	No
3gLM	Perilaryngeal	Self-energizing	Drainage channel	Yes	No

Table 1: Some features of the SADs presented.

Comparison with other Methods for Airway Management

The adoption of supraglottic airways has been growing rapidly, becoming especially popular for outpatient procedures, avoiding tracheal intubation [8]. By dispensing with the need of laryngoscopy and sometimes muscle relaxants, the risk of dental lesion, sore throat, myalgia, muscle weakness, nausea and vomiting is diminished. The insertion of an SAD is also generally less stimulating for the autonomic nervous system, resulting in fewer cardiovascular events [10,22,39]. Their use can lead to less time in the operating theatre, compared to those cases where tracheal intubation is preferred [58-60].

There appear to be some advantages in comparison with the face mask as well: a meta-analysis has revealed better oxygen saturation, more reliable performance under positive pressure ventilation (PPV), and less hand fatigue by the operator [22]. There were also less cases of jaw pain after the procedure but higher incidence of sore throat and dysphagia when using some SADs, related to the cuff pressure [61,62]. The need for endotracheal intubation is diminished when an SAD is used for PPV in neonates in place of a facemask [63].

Some of these advantages, especially the ease and speed of insertion, have led to some SADs being included in the algorithm for respiratory failure of the Advanced Cardiovascular Life Support (ACLS) guidelines: their use should be considered when face mask ventilation is not successful and after two or more failed attempts to place an endotracheal tube [43]. However, there is also evidence of severe and even life-threatening complications when an SAD is used by inadequately trained non-medical personnel in pre-hospital emergency care [64]. Additionally, after out-of-hospital cardiac arrest, there is evidence that patients handled with endotracheal intubation are more likely to return to spontaneous circulation and survive to hospital admission than those in which an SAD is used [65].

The main shortcoming of SADs, and the cLMA in particular, is the risk of pulmonary aspiration. This is due to the lower seal pressures, when compared with the ET [22]. On the other hand, the main upside of tracheal intubation is precisely the protection for pulmonary aspiration. Proper oesophageal sealing constitutes a barrier to the entry of regurgitated gastric fluid into the pharynx, likewise, peri-laryngeal sealing stops fluid from entering the airway. These minimize the risk, but depend on the shape and size of the device and the material which it is made out of. A softer, more malleable material is more likely to adjust to the pharyngeal wall, preventing the formation of gaps through which fluid can flow [66]. The correct placement is of paramount importance [67], and this should be assessed every time, which can be more easily done with later SADs, simply by advancing a gastric tube. There are several methods for determining seal pressure, of which at least four are successful and should be used regularly, aiding in assessment of correct placement [12,68]. The SADs with less risk of aspiration are those which show high pharyngeal and oesophageal sealing pressures, appropriate pharyngeal size, malleable material (regardless of being cuffed or not), and a draining channel.

Concurrently with the advantages demonstrated throughout the years, SADs have become indicated for a growing number of scenarios, including extremely invasive, prolonged surgeries (such as those of the heart [69]), certain laparoscopic procedures, and also obese patients [10,70]. This is especially true for the newer SADs, which have specific features for added safety [71]. However, there is no sufficient evidence to compare safety between the use of an ET and an SAD [7,72]. Given that the incidence of complications is exceedingly low - estimated risk of aspiration with an SAD ranges from 0.0009% [8] to 0.008% [73], randomised controlled trials able to evaluate and compare safety endpoints between the use of an ET and an SAD would require impractically large sample sizes.

Classifying SADs / In Search of A Possible Taxonomy

In the decades of 1990 and 2000 numerous new SADs have become available. The mechanism through which new devices are evaluated before being approved may be considered too loose [74], potentially leading to harmful consequences for patients. As examples, Alexiev et al. [75] and Michálek et al. [52] were the first to perform and publish clinical trials about the Baska Mask and 3gLM, respectively, several years after these were available in the marketplace. Until then, there were no published data about their clinical efficacy. Addressing this issue, Cook proposed a process similar to that of the evaluation of new pharmaceuticals, comprising three stages [74]. Only the successful completion of all three would lead to the approval to market the device. This would undoubtedly result in safer, more effective devices, but a new problem could arise, that of slowdown of innovation, due to the high costs manufacturers would have before marketing a new device. It is worth noting that to demonstrate efficacy a few studies with hundreds of uses might be enough, but only the data of thousands or hundreds of thousands of cases can prove safety. Hence, the true safety profile of a new device can only be known a long time after its adoption in clinical practice [7].

The ideal SAD must have high airway seal pressures during spontaneous and positive pressure ventilation, low resistance to the flow of gases, and some form of protection against pulmonary aspiration, including gastric drainage. Besides these design considerations, it should allow for perfect insertion rates at first try (both by non-medical staff in pre-hospital care and experienced anaesthetists), minimal rate of complications, and minimal incidence of post-operative symptoms. Moreover, it must be adequate for simple elective surgeries in low-risk patients and also, in selected patients and/or special scenarios be appropriate for complex laparoscopic surgeries in pregnancy or obesity, management of difficult airways and out-of-hospital rescue.

It is more likely that there are several devices perfectly adjusted for each of those than one single device for them all. This may explain why there are so many SADs. The need for a classification that is both easy to understand and helpful for selecting a device is clear, so that practitioners can more easily choose an SAD for their patient and their situation.

The first to propose a classification was Brimacombe, in 2004 [76], based on three criteria: whether the device has a cuff; if it is introduced through nose or mouth; and the anatomic location of the tip when correctly placed. The problem is that most of the devices used nowadays belong to the same group in this classification - cuffed, introduced through the mouth, tip at the entry of the oesophagus.

That same year, Miller proposed another system for classification [9], based on the sealing mechanism, placing all SADs in 3 groups: cuffed perilaryngeal sealers; cuffed pharyngeal sealers; and pre-shaped cuffless devices. Each of these groups had subgroups and then each device could be further categorized as reusable or single-use. This proved too complex however descriptive.

Hernandez tried to use the presence or absence of a cuff and the number of cuffs as a means to develop a nomenclature [12]. He divided all SADs into four groups, those with a single periglottic cuff, those with a single pharyngeal cuff, those with two cuffs regardless of their location of sealing, and those with no cuff at all. It is easy to understand and might be useful, when an SAD in one-group fails, ventilation might be possible with one of another group, because of a different sealing mechanism. However, it was not embraced among experts.

In 2011, Cook proposed a new classification [7], radically simple, dividing all SADs into 1st or 2nd generation devices. A first generation SAD is defined as being just a simple airway tube, with no specific design features for safety or performance. Second generation SADs, on the other hand, have been developed specifically for safety, with a gastric drain tube, improved pharyngeal seal and bite block. This was largely adopted by other authors [4,28,54].

Miller, though, felt this was too simplistic and proposed in 2014 yet another system [1], based on the sealing mechanism (three generations) and on the anatomic location of sealing (base-of-tongue or peri-laryngeal) (Table 2). The three generations of sealing mechanism are: 1) inflating mechanism, with one or more cuffs; 2) pre-shaped devices that fit into position; 3) automatic or self-energizing devices, in which airway pressure is transmitted to the inside of a flexible sealing element. Some, but not many, authors have adopted this [52,75].

	Location of Sealing	
Sealing Mechanism	**Peri-laryngeal**	**Base-of-tongue**
1st generation-inflatable cuff	cLMA, PLMA (§)	Combitube (§)
2nd generation-pre-shaped	i-gel (§, #)	SLIPA (§)
3rd generation-self-energizing	Baska mask (§, #)	-
(§)-Device has draining channel, (#)-Device can be used as a conduit for blind intubation		

Table 2: Examples of SAD according to Miller's new classification.

This sparked a debate between the two proponents of these different classifications, even with published letters to the editor of the British Journal of Anaesthesia [77,78]. Both sides show compelling arguments but both agree that each of their own systems have flaws, and that an all-encompassing classification is needed, which themselves - the specialists in the field - could agree on.

Conclusion

SADs are an important option for cases of difficult ventilation both in and out-of-hospital. They can be used as a conduit for tracheal intubation, or to replace the facemask, among other uses.

However, the most common use is as an airway in itself, during elective surgeries under general anaesthesia in patients with low risk of aspiration. There are a growing number of indications owing to the efficacy and safety that have been evidenced in multiple studies.

Unlike the endotracheal tube, whose design and features have not changed for decades, this method for airway management is still in development, with the introduction of new devices almost every year.

Thus, the need for taxonomy that serves as an organizational framework for all these devices, and helps with their selection for specific purposes are clear. Nevertheless, there is yet no consensus among the experts.

A thorough review of the regulations for designing and marketing a new SAD may be necessary, so as to ensure the safety of their use, based on reproducible scientific data.

In spite of the challenges in developing an SAD perfectly adapted to all procedures and patients, inventors and manufacturers continue to improve their designs, in search of the ideal SAD, which could potentially replace all others.

New devices are introduced every year, leading to the need for continuous learning by practising anaesthetists. Sound knowledge about the several SADs available and their specific features is essential to serve as the basis for an informed, well thought, and above all, safe anaesthetic practise.

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