Controversial issues in ambulatory anesthesia

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As day surgery expands, several aspects of patient selection and management become controversial. There are many controversies raging in ambulatory anesthesia, some are long-standing, and others are relatively new. In the interest of brevity, we have chosen to focus on two distinct areas, namely the use of depth-of-anesthesia monitoring to titrate ambulatory anesthesia and the management of the airway.

Depth-of-anesthesia monitoring

The guiding principle of ambulatory anesthesia is the provision of surgical anesthesia that results in a rapid emergence and recovery, with adequate analgesia and rapid patient turnover at low cost, culminating in early and safe home discharge. This has placed considerable demands on the anesthetist to achieve these ideals without compromising patient comfort and safety. The task has been compounded by many obstacles, the most important of which is the lack of precise pharmacological knowledge of the mechanism of action of anesthetic drugs on the target organ, the brain. To date, the direct effect of these drugs cannot be measured objectively. Consequently, anesthetic drugs are titrated against surrogate measures of their effect. The most common of these reflect cardiovascular toxicity [1], although markers of cerebral depression are also used.

Since the beginnings of anesthesia, awareness with recall of intraoperative events has been a major concern. Awareness is a frightening experience that may result in serious psychological trauma and is a common cause of litigation [2,3]. The “holy grail” of anesthesia has been to develop a monitor to prevent
awareness, and several devices that may serve such a function are at various stages of clinical development [4]. Although the incidence of awareness with explicit recall during anesthesia for noncardiac surgery has been reported to be as high as 1:1,000 to 1:500 [5,6], those monitors that are already commercially available have not been embraced as readily as might be expected. This may be because of concerns over the reliability of the technology, beliefs that awareness is an unlikely complication, or simply an unwillingness to invest in these expensive new monitors.

Because an awareness detector must in some way monitor the “depth of anesthesia,” it is logical that these devices could be used to titrate anesthetic drugs so that the lowest amounts necessary to achieve unconsciousness were delivered. This would improve recovery, might reduce adverse effects, and could reduce costs (through lower drug consumption) despite the additional costs of monitoring. It is this potential for producing clinical and financial benefits for all patients that has driven the adoption of depth-of-anesthesia monitoring in ambulatory practice, and has also generated the greatest controversy. The bulk of the evidence to date relates to the bispectral index (BIS), as this was the first practical monitor to become commercially available.

Bispectral index

Because the brain is a likely target of anesthetic action, most depth-of-anesthesia monitors have focused on changes in the EEG. Simple measures, such as spectral edge frequency (SEF), have long been available but suffer from a lack of reproducibility and changes that are not independent of the specific anesthetic agent used. The bispectral index (Aspect Medical Systems, Newton, MA) overcomes some of these limitations by using a commercial algorithm to generate a linear dimensionless number (ranging from 0 to 100) that decreases in magnitude with increasing anesthetic depth. BIS correlates well with clinical endpoints of sedation and loss of consciousness [7] and is relatively agent independent [1]. Although the BIS monitor still suffers from some of the limitations of EEG monitoring (including poor signal strength and susceptibility to electrical “noise”), it is relatively easy to set up and interpret [1].

A BIS value below 60 is associated with “a very low probability of response to verbal command” [1], yet in practice, clinical titration of anesthetic agents usually results in far lower values. Though this should make awareness unlikely, it implies excessive anesthesia, which may increase adverse effects and delay recovery. Maintaining BIS at values closer to 60 might avoid some of these problems, while still avoiding awareness.

Gan and colleagues titrated propofol-alfentanil to achieve BIS scores of 45 to 60 during anesthesia, and 60 to 75 toward the end of anesthesia, and compared this with standard practice [8]. Clinical titration resulted in “deeper” anesthesia, with BIS values in the range of 40 to 45. Titration to BIS reduced propofol consumption by 23%, reduced emergence times by 3 to 5 minutes, almost doubled the proportion of patients who were oriented on reaching the recovery room, and
reduced discharge times by 6 minutes [8]. Adverse events did not differ between the two groups. In a similar study design, Song and colleagues titrated sevoflurane or desflurane against clinical signs or to maintain a BIS value of approximately 60 [9]. Again, anesthesia was deeper in the control group, with mean BIS values of 42, whereas maintaining values of 60 reduced anesthetic consumption by 31% to 38% and reduced emergence times by 30% to 55% [9]. High BIS values toward the end of anesthesia have been shown to correlate with the ability to bypass the recovery room (so-called “fast-track recovery”), although the effect of titration to specific BIS values on fast-track recovery rates was not assessed [10]. Other workers have failed to detect any correlation between BIS values at the end of anesthesia and individual awakening times [11]. Evidence that BIS monitoring may reduce dose-dependent side effects is provided by a reduction in postoperative nausea and vomiting, as well as earlier awakening, when sevoflurane delivery was titrated to maintain a BIS of 60 compared with standard practice [12]. Other workers have failed to detect any reduction in adverse events [8,9].

Not all investigators have demonstrated advantages to BIS monitoring. BIS is not entirely agent independent and does not reflect the clinical effects of nitrous oxide (N₂O) particularly well [13]. When propofol with or without N₂O was titrated against BIS values, the amount of propofol delivered in the two groups did not differ [14]. This was probably because the BIS was only registering the propofol component of anesthesia, encouraging the investigators to deliver more than was actually needed in the presence of N₂O. Because the N₂O would have contributed to the anesthetic state, even if not measured by BIS, it is not surprising that recovery was delayed in this group [14]. BIS monitoring may be less helpful when N₂O comprises a significant part of the anesthetic. Problems may also be encountered when using differing combinations of hypnotics and opioid analgesics [4].

**BIS and conscious sedation**

BIS may also have a place in the titration of sedation during procedures performed under local or regional anesthesia. With increasing concentrations of sedative drugs, BIS correlates well with the level of patient responsiveness and loss of consciousness [15,16]. During surgical procedures performed under regional anesthesia, learning seems to be suppressed once BIS levels reach 91 or lower [17]. As values decrease further to 70 to 80, patients become progressively drowsier but should still be rousable. BIS monitoring may be useful in patients who do not want intraoperative amnesia, in whom it would be necessary to maintain almost awake values. In other circumstances, the clinical condition of the patient may be just as useful, and it remains to be shown whether BIS will prove to be a valuable sedation monitor.

**Controversies of BIS monitoring**

The controversies surrounding BIS monitoring relate to its cost-effectiveness and its reliability. BIS is an expensive monitor. In addition to the initial purchase
cost of the device itself, specialized disposable electrodes are required for every patient. These simplify the initiation of monitoring and are purported to improve the signal quality, although the cost is high at $10 to $20 each. Recently, however, the electrode impedance and BIS value were found to be identical, irrespective of whether the dedicated BIS sensor or standard ECG electrodes were used [18]. It is unlikely that the manufacturer of the BIS monitor will endorse the routine use of such inexpensive electrodes, and the current design of the monitoring lead makes this difficult without significant modification.

The cost of BIS monitoring is usually justified by the potential for savings in drug costs and recovery time resulting from its use, although formal cost-effectiveness analyses have not been performed. Though large percentage reductions in anesthetic drug requirements have been demonstrated [8,9], the availability of generic propofol at lower cost and the use of low fresh-gas flows with volatile agents will all reduce the absolute savings somewhat. Mathematical modeling has demonstrated that the reductions in emergence times that BIS monitoring may be able to achieve do not result in any savings with salaried staff and only reduce staffing costs if workers are paid at hourly rates [19]. Even then, the reductions are relatively modest, probably only $1.50 to $5 per patient [19], substantially less than the cost of the disposable electrodes. Currently, the economic and outcome benefits of BIS are not clearly established [20].

Greater concern relates to the reliability of BIS. At a population level, BIS does appear to correlate well with clinical indices of sedation [7,16,21]. This is hardly surprising, because the BIS algorithm was developed and refined to provide a “best fit” between the electrical signal from the patient and the subjective opinion of their anesthetist as to their anesthetic state at that time [22]. However, there is considerable individual variation [7,16], suggesting that we can be far less certain of the adequacy of anesthesia in any particular patient. Furthermore, the BIS algorithm has been frequently revised over the years so that there is considerable uncertainty as to whether earlier results are still valid [20]. BIS does not predict movement at skin incision [16], although opinion is currently divided as to whether this makes it any less reliable at detecting awareness. Last year, Aspect Medical Systems, the manufacturer of BIS, had reports of only 41 cases of awareness in over 1.2 million patients who were BIS monitored, many of which had BIS values greater than 65 [23]. This is far lower than the incidence of awareness reported in the literature. Though this may reflect the efficacy of BIS in preventing awareness, it may simply represent under-reporting or could be the result of other differences in technique between early adopters of this new technology and the remainder of the anesthesia community. A large multicenter study in a high-risk patient population is currently underway in Australia, New Zealand, and Hong Kong to try to establish convincing evidence that the routine use of BIS monitoring is beneficial in reducing the incidence of awareness and drug and recovery room costs [23].

Even if BIS can reliably define the line between unconsciousness and awareness, there is still a fundamental difference in philosophy between using it to keep the patient on the right side of that line and using it to place an individual
patient as close to the line as possible [4,20]. Even if the position of the dividing line can be accurately defined for every patient (and there is considerable doubt that it can be), titration to BIS may encourage anesthetists to maintain general anesthesia at such light planes that, should anything go wrong with drug delivery, there will be little time to take any corrective action before awareness occurs [22].

Other depth-of-anesthesia monitors

There are a wide variety of other devices undergoing development as potential depth-of-anesthesia monitors. Several of these also involve recording and processing the EEG signal. One monitor undergoing development by Physiometrix (North Billerica, MA) uses quantitative techniques to examine the EEG from various regions of the brain. The distribution of EEG power changes with varying sedative states and is to some degree independent of the anesthetic used [24]. This principle has been further developed to produce a Patient State Index (PSI), which, like BIS, ranges from 0 to 100 with lower values indicating increasing sedation. Unlike BIS, PSI values are typically 25 to 50 during the maintenance phase. Collecting the signal requires a special flexible plastic strip, similar to the BIS monitoring electrode but incorporating seven electrodes in a fixed arrangement. The Patient State Index is still at an early stage of development and there are limited comparative trials with other techniques, although it is now commercially available.

More work has been done with auditory-evoked potentials (AEP). This technique still involves an EEG recording but, in this case, the specific response to an auditory stimulus, in the form of a click played through headphones, is sought and averaged by a computer. Unlike previous monitors, the AEP measures the effect of anesthetics on a defined anatomical pathway, although almost certainly not the one producing unconsciousness. With increasing levels of anesthesia, the amplitude of the early cortical response decreases and its latency increases, allowing a simple index to be calculated. This value, the auditory evoked potential index (AEPI), decreases in magnitude with increasing depth of anesthesia. Preliminary studies have shown that the AEPI is more reliable than BIS at distinguishing the transition from consciousness to unconsciousness [25], at least with propofol anesthesia. It may also provide better discrimination in individual patients than BIS [26]. More recent work has shown that the index can also reliably discriminate between awake and unconscious states with sevoflurane anesthesia [27]. A commercial monitor, the A-line ARX® (Alaris Medical Systems, Basingstoke, Hampshire, United Kingdom), is now available and features more rapid extraction of the AEP signal compared with earlier devices [28], allowing virtually real-time monitoring of the depth of anesthesia. In contrast to earlier work, this revised AEPI correlated slightly less well than BIS with calculated propofol effect site concentration, loss of the eyelash reflex, and a clinical sedation scale, and also demonstrated greater interpatient variation [28]. Neither AEPI nor BIS predicted patient responses to noxious stimuli, but the former increased more rapidly compared with BIS in the presence of arousal [28], a potential advantage in the early detection of awareness or in rapid titration of anesthetic drugs.
It is likely that the AEPI could be used to guide anesthetic delivery to reduce excess drug administration and improve recovery in a similar way to BIS. However, such studies do not appear to have been performed and no such comparisons have been made with BIS. The AEPI is not a perfect anesthesia monitor, as it shares the limitations of EEG monitoring with BIS. Access is required to the patient’s ears to deliver the clicks, and the monitor will not work if the auditory pathway is not intact (e.g., in deaf patients).

**Autonomic monitors**

Several workers have attempted to detect changes in autonomic function as indices of anesthetic adequacy. Monitors of lower esophageal contractility have now been discredited, but heart rate variability (HRV) seems more promising. Heart rate variability is a normal feature. It exists in a variety of forms, but respiratory sinus arrhythmia (RSA), the change in heart rate with respiration, is the best known. RSA is decreased with increasing anesthetic concentrations [29], suggesting that it would be a good candidate for a depth-of-anesthesia monitor. Furthermore, RSA can be measured using standard ECG electrodes, which provide a large signal (relative to the EEG) and are already in routine use. Deriving a useful index of heart rate variability in real time is technically complex, but the major problems appear to have been overcome and at least two monitors are under commercial development (Fathom®, Amtec Medical, Antrim, United Kingdom, and Anemon®, Medical Control, Geneva, Switzerland). There are promising early results, but again, widespread comparisons with other techniques have yet to be conducted. Like AEP, HRV measures a physiological response, unlike the empirically derived BIS. Although HRV overcomes some of the problems of EEG recording, autonomic nervous system diseases, lesions of the vagus nerves, or a transplanted heart render it useless.

**Summary: depth of anesthesia**

The prospect of a reliable depth-of-anesthesia monitor is better now than it has been for many years. A number of devices are commercially available and appear to correlate well with the clinical anesthetic state, at least at population level. All have some limitations, however, and their absolute reliability is as yet unknown. It is likely that the “ultimate” monitor will combine elements of some, if not all, of the currently available devices.

Of more fundamental concern is that the underlying argument for anesthetic depth monitoring has been usurped. These monitors were intended to improve patient care by further reducing the already low chance of awareness during surgery, a potentially avoidable complication with major consequences. They are currently being used not to reduce the risk of harm but to reduce costs by deliberately reducing the amount of anesthesia delivered. Although there is no evidence that it has happened so far, there is the distinct possibility that this use of these monitors will actually increase the risk of a patient being aware [4,20,22].
the very thing they were designed to prevent. This is perhaps even more likely in everyday clinical practice, where patients may have preexisting medical conditions or be receiving medications (or combinations of medications), which were excluded during the careful clinical trials on which most evidence is based [4]. We must be very careful in how we apply this technology, especially before its efficacy in achieving its original purpose has been adequately determined.

Airway management

The range of airway management devices has expanded considerably from the original choices of tracheal tube or face mask. With greater choice comes controversy as to the relative advantages and disadvantages of each type of airway, as well as the range of procedures for which they are appropriate. The use of the laryngeal mask airway (LMA) in ambulatory surgery is far from controversial; the device has been a major success story and is currently used in the vast majority of such procedures, at least in the United Kingdom. Areas of controversy do still exist, however, most notably the use of the LMA during laparoscopy and in the prone position.

Simple laparoscopy with the LMA

The use of the LMA (Intavent Orthofix, Maidenhead, Berkshire, United Kingdom) during gynecological laparoscopy was initially controversial, although this is less so now in the light of continuing experience. The risk of aspiration was thought to be increased by the pneumoperitoneum and by head-down tilt. Both maneuvers increase lower esophageal pressure more than intragastric pressure [30,31], strengthening the barrier pressure and providing protection against regurgitation. Continuous esophageal pH monitoring failed to detect significant gastroesophageal reflux during laparoscopy managed with the LMA [32,33]. Randomized controlled trials have shown that the LMA can achieve satisfactory surgical conditions for laparoscopy [34,35], and the low risk of adverse events is confirmed by two large series [36,37].

There may be more controversy over the choice of controlled or spontaneous ventilation, as the pneumoperitoneum, absorption of CO₂, and adverse patient positioning all compromise ventilation. Although statistically significant changes in end-tidal carbon dioxide tension and arterial pH occur during spontaneous ventilation, these are small in magnitude and correct rapidly following release of the intraabdominal gas [38]. Spontaneous ventilation through the LMA produced no clinically significant adverse effects [34,35] and was no more likely to result in subclinical regurgitation, compared with controlled ventilation [39]. The use of neuromuscular block does not reduce intraabdominal pressure [40].

Despite the apparent advantages of the LMA in laparoscopy, including lighter anesthesia and avoidance of neuromuscular block, use of the LMA was recently found to be associated with a twofold increase in the risk of unanticipated admission following ambulatory gynecological surgery [41]. The LMA was very
commonly used for this form of surgery in the survey, which may explain the apparent association.

Extended laparoscopy

Much of the considerable experience accumulated with the LMA in laparoscopy comes from its use in brief procedures. Although there is no definitive proof, much of the safety of this technique is thought to depend on short operating times of 15 minutes or less, less than 15 degrees of table tilt, and intraabdominal pressures less than 15 mmHg. With the development of microlaparoscopes, many of these short and simple procedures no longer require general anesthesia and are being moved to the office setting [42]. They are being replaced by more prolonged and complex procedures, where the safety of the LMA is largely unknown.

Laparoscopic cholecystectomy

The head-up position, which is commonly used during laparoscopic cholecystectomy, may be more mechanically favorable for the LMA compared with pelvic laparoscopy. In contrast, the longer duration of the procedure combined with greater disturbance of the upper gastrointestinal tract probably increase risk. The LMA was first used for laparoscopic cholecystectomy shortly after its introduction, and a case of aspiration pneumonia was reported early on [43]. Successful use without clinically significant adverse events was reported in a small series of 65 patients [37].

A randomized controlled trial compared ventilatory parameters and surgical conditions during laparoscopic cholecystectomy when the airway was maintained with an LMA or a tracheal tube [44]. Oxygen saturation, expired CO₂ and airway pressures did not differ between the groups during controlled ventilation and neither the incidence nor degree of gastric distention were influenced by the choice of airway [44]. Though this study provides good evidence for the efficacy of the LMA during laparoscopic cholecystectomy, the sample size was too small to provide any evidence on safety. This is still a controversial issue, with some experts claiming the LMA to be contraindicated during this procedure [45,46], whereas others do not [47]. The major areas of concern is that reflux of bile and, where it is used, cholangiogram contrast material increase gastric volume and that bile produces especially severe pulmonary damage when it is aspirated [46]. Common sense would suggest that the LMA should probably not be used for laparoscopic cholecystectomy until its safety is clearly established in large-scale trials.

The availability of the Proseal LMA (Intavent Orthofix) may change this view because its design should permit better drainage of gastric contents and afford greater protection against aspiration [48]. Two large studies have shown greater seal pressures with the ProSeal LMA than those achieved with the standard device [49,50]. Though some workers have shown the ProSeal to be slower and more difficult to insert [49,51], others have not experienced such difficulties [50]. Recently, the ProSeal LMA has been compared with the standard
LMA during laparoscopic cholecystectomy [51]. In contrast to previous work, ventilation through the standard LMA was judged to be inadequate in some patients following the establishment of pneumoperitoneum, whereas conditions always remained favorable with the ProSeal [51]. As expected, seal pressure was substantially higher with the ProSeal and a gastric drainage tube could be correctly placed in all 40 patients. Of those patients, 78% were found to have residual gastric fluid, which was bile stained in almost half the cases, yet none were clinically considered to be at risk of aspiration [51]. The authors acknowledged that the actual risk of pulmonary aspiration was unknown, but concluded that the ProSeal was a more effective ventilatory device [48]. Further experience is required before any change of practice may be recommended.

**The LMA in the prone position**

The use of the LMA in the prone position is controversial. Some case reports and a few small series have been published on the LMA in the prone position [52,53], but no large-scale clinical trials have been done. Personal experience suggests that the practice is widespread, however. As in other uses, the LMA works well in association with spontaneous ventilation. The patient must be adequately supported, with sufficient clearance under the abdomen to allow adequate breathing [53]. With the patient correctly positioned, the airway is as clear through an LMA as with a tracheal tube; a reinforced LMA avoids the risk of kinking. Skeptics often voice concern over the “disastrous consequences” of the LMA “falling out” while the patient is face down. It should always be possible to secure the LMA firmly so that it is no more likely to be displaced than a tracheal tube, but if the airway is extruded, spontaneous breathing should ensure that the patient remains adequately oxygenated. It is also far easier to replace the LMA than to reintubate a prone patient. Some workers routinely ask the patient to position themselves in a comfortable prone position before inducing anesthesia. The LMA is subsequently inserted by turning the patient’s head to the side [53–55]. Such an approach avoids having to manhandle an unconscious patient and substantially reduces the risk of serious injury to patient and staff [53].

**Newer airway devices**

Since the amazing success of the LMA, numerous attempts have been made to invent a better airway device. To the current authors, this seems a futile exercise, given that the LMA suffers from relatively few faults. The inability to protect against aspiration of gastric contents is an obvious failing, but one that most “alternatives” have not attempted to address. The LMA is easy to insert and atraumatic, though a lower incidence of throat soreness would be desirable. There has been some concern in the United States that the device was reusable (although sterilized before reuse), but its nondisposability has not been an issue elsewhere. No reports of patient-to-patient contamination have appeared with the LMA in
over 10 years of use. Disposable items are often more expensive (per patient) than reusable ones and contribute significantly to environmental pollution.

Several alternative airway devices have been developed. Some of these are reusable and others are disposable, the best known of which is the cuffed oropharyngeal airway (COPA).

The cuffed oropharyngeal airway

The cuffed oropharyngeal airway (COPA®, Mallinckrodt Medical, St. Louis, MO) consists of a Guedel-shaped airway with an inflatable cuff to displace the tongue and help retain the device in position. At the other end is a 15-mm connection to attach to a standard breathing circuit. The COPA is inserted like a conventional oral airway and retained with an elasticated strap, after which the cuff is inflated, using 25 to 40 mL of air. The COPA is available in various sizes which are color coded for convenience. The size required is based on the distance between the incisor teeth and the angle of the mandible, although choosing the correct size can be problematic [56,57].

The COPA seems more difficult to insert compared with the LMA. The developer’s own work revealed a significantly lower first-time success rate with the COPA (81% versus 89%), which significantly delayed the establishment of an effective airway 106 to 150 seconds [58]. These workers had relatively little experience with the LMA, but could be assumed to be proficient with the COPA. When a similar comparison was performed by investigators experienced in the use of the LMA, even more striking results were obtained. The LMA was successful the first time in 97% of patients compared with only 55% with the COPA [57]. A different-sized COPA to that originally selected was required in 27% of patients and the time to establish a patent airway was dramatically longer with the COPA (188 seconds) compared with the LMA (49 seconds) [57]. Insertion of the COPA is also no less invasive compared with the LMA, in terms of hemodynamic response or change in BIS [59].

Once in place, the airway produced by the COPA appeared greatly inferior to that obtained with the LMA and required more effort to maintain. Only 4% of patients managed with the LMA required any manipulations of the airway during the maintenance phase and, at most, only two manipulations were required [58]. In contrast, one or two manipulations were required by 35% in the COPA group, more than two by a further 36%, and continuous support was required in almost 30% [58]. Overall, the LMA produced an “excellent” airway in almost 77% of patients, compared with just over 25% with the COPA [58].

On the basis of these findings, it is difficult to see any obvious place for the COPA in routine ambulatory practice.

Airway Management Device

The Airway Management Device (AMD) is a new, reusable device comprised of a silicone tube with two inflatable cuffs. The distal cuff lies at
the top of the esophagus and occludes it; the proximal cuff pushes the base of
the tongue forward, lifting the epiglottis [60]. An opening between the two
cuffs allows ventilation of the larynx. The manufacturers (Nagor, Isle of Man,
United Kingdom) claim that the device, which is intended for use during
spontaneous or controlled ventilation, “is easy to insert and provides a reliable,
reproducible, patent and clear airway” (Nagor AMD information leaflet,
distributed 2001).

No clinical trials of this device were published before its marketing, but an
independent evaluation has now been performed on 105 patients. The device
could be inserted in all patients following induction of anesthesia with propofol
and an opioid, but the airway was only fully patent in 85 (81%), partially
obstructed in 10, and completely obstructed in another 10 [60]. Significant
numbers of airway manipulations were required to achieve or maintain a patent
airway and the airway subsequently became obstructed in two patients during
maintenance and three during emergence [60]. The AMD was usually easy to
insert and rarely caused throat soreness, but its reliability was poor with a high
rate of failure to maintain a patent airway and a tendency for this to be lost on
patient movement [60]. A small evaluation on 50 patients has confirmed
similar problems with adequate airway patency [61]. Concern has also been
raised about the high pressures sometimes required in the pharyngeal cuff
[60,61], and severe congestion of the tongue has already been observed
[61,62]. Although the inventor of the AMD claims the device is reliable and
safe [63], others do not share this view [64]. The available evidence to date
would suggest that this product offers no major advance over the LMA and, at
present, there is far too little experience available to prove either its safety or
reliability. As with the COPA, it cannot currently be recommended in
ambulatory anesthesia.

Laryngeal tube

The laryngeal tube® (VBM, Sulz, Germany) is based on an esophageal
obturating airway. It is similar in appearance to the AMD, is also made of silicone,
and is reusable, but does not have a distal port for esophageal suction. One
preliminary study showed that the device was easy to insert and could facilitate
controlled ventilation in 94% of patients [65], though it was not evaluated for
maintenance of anesthesia. A second noncomparative evaluation showed suc-
cessful insertion and adequate ventilation for 10 minutes in 30 healthy adult
patients [66]. In contrast, a randomized trial comparing the laryngeal tube with
the LMA was abandoned after only 34 patients [67]. This was due to failure to
achieve a patent airway with the laryngeal tube in 10 of the 17 patients (59%)
randomized to this device. In all these cases, use of the laryngeal tube was
abandoned and an airway was successfully established with the LMA [67].
Despite the promising initial results, this would appear to be another device with
little place in ambulatory anesthesia, unless subsequent trials show far lower
failure rates.
Streamlined pharynx airway liner

The streamlined pharynx airway liner (SLIPA®, SLIPAmed, Cape Town, South Africa) is another alternative airway device undergoing evaluation. It is comprised of a soft plastic, preformed hollow “bootlike” device that lines the pharynx [68]. It has no cuff, as its shape is said to conform to the larynx. One limited evaluation showed the device to be successful in 20 of 22 patients, it was abandoned in the remaining two (9%) [68]. This device is still at the prototype stage and its eventual place is far from clear. It is likely that, in the absence of an inflatable cuff, many different sizes will be required to ensure an adequate seal [68], although manufacturing costs are anticipated to be low. It will be some time before any recommendations can be made regarding this device.

Summary: airway devices

Inventors will no doubt continue to produce alternative airway devices, and some will be marketed. Perhaps the greatest controversy is that in contrast to the pharmaceutical industry, the producers of airway adjuvants (and other medical devices) appear to be under no constraints to produce evidence for the efficacy or safety of their products before the granting of a manufacturing license. Consequently, new devices appear on the market, often accompanied by extravagant claims as to their ease of use, safety, and reliability, yet supported by little or no reliable data. Anesthetists are cautioned to be extremely wary of such new equipment and to not risk patient safety until adequate experience has been collected and published in properly conducted clinical trials. For the moment, the LMA is well established, but the same cannot be said of most alternatives.

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