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PATIENT SAFETY: STRATEGIES TO REDUCE ANAESTHETIC RISKS

LD Mishra[1], Badri P Das[2]

Patient safety relates to the reporting, analysis, and prevention of medical error that often leads to adverse healthcare events. The pursuit of patient safety involves reducing the gap between best practice guidelines and the care actually delivered to patients. Patient safety in anesthesia, by definition, involves actions taken by anaesthetists and hospital organizations to protect patients from being harmed by the effects of anaesthetic drugs and services. Recognizing that healthcare errors may impact as high as 1 in every 10 patients around the world, the World Health Organization calls patient safety an endemic concern[1]. Indeed, patient safety has emerged as a distinct healthcare discipline supported by an immature, yet developing scientific framework. There is a significant transdisciplinary body of theoretical and research literature that informs the science of patient safety[2].The resulting patient safety knowledge continually informs improvement efforts such as: applying lessons learned from business and aviation industry, adopting innovative technologies, educating providers and consumers, enhancing error reporting systems, and devising new strategies to address these failures. Understanding how to reliably deliver best practice care using established anaesthetic techniques may, today, be more important than seeking new ones.

PREVALENCE OF ADVERSE EVENTS

Millennium ago, Hippocrates recognized the potential for injuries that may arise from the well-intentioned actions of healers. Greek healers in the 4th century BC drafted the Hippocratic Oath and pledged to "prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone". Since then, the directive primum non nocere (“first do no harm”) has become a central tenet for contemporary medicine. In 1949, Robert Macintosh challenged the prevailing view that deaths under anaesthesia were inevitable, contesting they were frequently attributable to anaesthetists' failures[3]. However, despite an increasing emphasis on the scientific basis of medical practice in Europe and the United States in the late 19th Century, data on adverse outcomes were hard to come by and the various studies commissioned collected mostly anecdotal events[4]. In 1983, the British Royal Society of Medicine and the Harvard Medical School jointly sponsored a symposium on anesthesia related injuries and deaths, resulting in an agreement to share statistics and to conduct studies. By 1984, the American Society of Anesthesiologists (ASA) had established the Anesthesia Patient Safety Foundation (APSF), a notable milestone in this journey, which used the term "patient safety" for the first time in the name of professional reviewing organization[5]. Likewise, the Australian Patient Safety Foundation was founded in 1989 for anesthesia error monitoring. Both organizations, along with Confidential Enquiry into Perioperative Deaths (CEOPD) in UK in 1987, have identified a

1. MD, PhD, FICA; Professor & Head
2. MBBS; MD (Anaesth) student & III Year Junior Resident

Department of Anaesthesiology, Institute of Medical Sciences, Bananas Hindu University, Varanasi-221 005.

striking similarity among aviation and anaesthesia in that, more than 80 % of aircraft accidents occur during landing and more than 80% anaesthetic accidents occur only during recovery[5]. This similarity emphasized "preparedness" needed in both. The full magnitude and impact of errors in health care was not appreciated until the 1990s, when several reports brought attention to this issue[6]. In 1999, the Institute of Medicine (IOM) of the National Academy of Sciences, USA released a report, "To Err is Human: Building a Safer Health System"[7] and called for a broad national effort to include establishment of a Center for Patient Safety, expanded reporting of adverse events, development of safety programs in health care organizations, and attention by regulators, health care purchasers, and professional societies.

CAUSES OF HEALTHCARE ERROR

The simplest definition of a health care error is a preventable adverse effect of care or failure to perform an action as planned or intended to, whether or not it is evident or harmful to the patient. Most errors have been attributed to[8,9]:

(A) Human Factors: (>70%)

1. Variations in healthcare provider training & experience, fatigue & depression.
2. Diverse patients, unfamiliar settings, time pressures.
3. Failure to acknowledge the prevalence and seriousness of medical errors.

(B) Medical complexities

1. Complicated technologies, powerful drugs.
2. Complexities of intensive care, prolonged hospital stay etc.

System failures

1. Poor communication (between healthcare providers, or between providers and the patient and family members) being the most common cause[10], unclear lines of authority of physicians, nurses, and other care providers.
2. Complications increase as health care provider to patient staffing ratio decreases.
3. Disconnected reporting systems within a hospital: fragmented systems in which numerous hand-offs of patients results in lack of coordination and errors.
4. Drug names that look alike or sound alike.
5. The impression that action is being taken by other groups within the institution.
6. Reliance on automated systems to prevent error.
7. Inadequate systems to share information about errors hamper analysis of contributory causes and improvement strategies.
8. Cost-cutting measures by hospitals in response to reimbursement cutbacks.

9. **Environment and design factors:** In emergencies, patient care may be rendered in areas poorly suited for safe monitoring.

10. Infrastructure failure: According to WHO, 50% of medical equipment in developing countries is only partly usable due to lack of skilled operators or parts. As a result, diagnostic procedures or treatments cannot be performed, leading to substandard treatment.

Although anaesthesiologists make up only about 5% of physicians in USA, anaesthesiology is acknowledged as the leading medical specialty in addressing issues of patient safety[6]. Why is this so? Firstly, as anaesthesia care became more complex apply, technological and expanded to include intensive care, it attracted a higher calibre of staffs who tend to be risk averse and interested in patient safety because anaesthesia can be dangerous but have no therapeutic benefit of its own. Secondly, in the 1970s and '80s the cost of malpractice insurance for anaesthesiologists soared and was at risk of becoming unavailable, which galvanized the profession at all levels, including grass root clinicians, to address seriously issues of patient safety. Thirdly, perhaps most crucially, strong leaders emerged who were willing to admit that patient safety was imperfect and that, like any other medical problem, patient safety could be studied and interventions planned to achieve better outcomes.

The incidence of medical errors in anaesthesia is increasing and is likely greatly underestimated and under-reported. Furthermore, these problems have plagued anesthetists since the advent of our specialty with publications regarding such problems first appearing in the 1950's[11]. In 1984, Cooper et al published that medication errors (mostly drug syringe swaps) remain a leading cause of morbidity and mortality in hospitalized patients[12], which are magnified during the perioperative period given the frequent use of numerous medications, the rapidity with which medications are prepared and administered as well as the general pace of the high acuity situations[13]. Also, those medications may have to be given in an environment of poor visibility with multiple distractions[14,15]. Other errors occur more often with breathing circuit disconnections, gas flow control or loss of gas supply, although these are less now with advanced anaesthesia workstations.

Risk is ubiquitous in medicine but anaesthesia is an unusual speciality as it routinely involves deliberately placing the patient in a situation that is intrinsically full of risk. Patient safety, depends on management of those risks; consequently, anaesthetists have been at the forefront of clinical risk management (CRM).Clinical risk management in anaesthesia and critical care can be described in five stages: risk awareness, risk identification, risk assessment, risk management and re-evaluation.

RISK AWARENESS

A simple definition of clinical risk is the potential for unwanted outcome. In the context of anaesthesia, injury can range from temporary discomfort, such as nausea in recovery, to permanent disability or death. The patient can be viewed as being in the centre of a web of complex interactions between disease process, medication, the anaesthetist, equipment and other members of the healthcare team; this complexity brings risk. CRM starts with awareness that these risks exist which may lead to compromises in patient safety, and patient safety incidents (PSI) will inevitably occur through mistake, accident or mishap, unless appropriate risk management strategies are implemented. A PSI may be defined as any unintended or unexpected incident that could have, or did, lead to harm ("critical incident"). The Department of Health estimates that about 10% of inpatients experience a PSI out of which about 50% are preventable, causes being inadequate communication followed by lack of clear policies or guidelines, deficient working practices, poorly defined responsibilities or inadequate training or supervision[8,9].

RISK IDENTIFICATION

There are a number of methods for identifying clinical risks, both retrospective and prospective.

RETROSPECTIVE IDENTIFICATION

1. Patient safety incident reporting

Most institutions now have well-developed incident reporting systems, but these are dependent on staff identifying and reporting relevant incidents. Voluntary incident reporting alone only captures a minority of PSIs, and it appears that there are many barriers to reporting. A variety of techniques to formalize reporting have been tried and tested, including automated reporting of pre-defined events from computerized anaesthetic charts[16] but none is all encompassing. PSI data are usually collected centrally within an institute on a database that can be interrogated to identify trends or high-risk areas and activities, and reviewed regularly, at department level, so that feedback can be given to staffs who report the incidents. A "no-blame" or "just-blame" culture that encourages reporting

and separates the process of incident reporting from disciplinary procedures, that has in the past inhibited staff from reporting adverse events, is essential[14]. Errors should be openly reported and discussed without fear of retribution, penalties, or loss of employment. This allows for the identification of where the system failed, appropriate reporting of problems, and the development of strategies to prevent such incidents from recurring.

The National Patient Safety Agency (NPSA) has established the National Reporting and Learning System to which all institutions now submit incident data on a routine basis, with an aim to assist the NHS to learn as an organization about high-risk activities, and to recognize and focus on "clusters" and inform the publication of "Patient Safety Alerts" that make recommendations for improving safety. This model of national collation of PSI reports is not new and has been shown to be effective: the best known example being the Australian Incident Monitoring Study (AIMS) database[17], started in 1987 and by 2001 had collected 8088 PSIs. A lot of issues have been successfully examined by selecting records from this database, including the applications and limitations of pulse oximetry, fatigue in anaesthetists, cardiac arrest, drug errors, awareness under anaesthesia and aspiration.

2. Complaints and claims

Lessons may also be learned from litigation, although these incidents are highly selected compared with anonymous "just-blame" reporting. The American Closed Claims Analysis started in 1985, have given insight into issues such as the role of monitoring in the prevention of anaesthetic mishaps and airway damage during anaesthesia[9].

3. Retrospective case note review

Major publications in the late 80s and early 90s, relied on a two-stage retrospective case note screening technique to identify adverse events[18,19]. Routine mortality audit is an example and, when undertaken in an open and learning environment, can be very effective.

4. Root cause analysis (RCA)

It is a structured investigation that aims to identify the true cause of a problem, and the actions necessary to eliminate it[20]. While incident reporting identifies latent factors, ideally before harm occurs; RCA, in contrast, is usually carried out in response to harm. It is much more time and labour intensive than routine departmental procedures but provides a thorough and formal analysis of why it has occurred and how it may be prevented in the future, rather than a quick fix focused on the most obvious symptom. It includes 4 stages:

i. Data collection: from local protocols to switchboard records. The patient's whole admission is considered, not just the PSI.

ii. Presentation of information so that problems can be identified: simple chronological narrative or a tabular timeline what each person involved in the incident was doing for each 5 min block of time.

iii. Root cause identification: "Whys" describes a process where one does not accept the first answer for a root cause and keeps on asking why each cause happened until all agree that the fundamental cause has been identified. Barrier Analysis looks at the control measures in place to prevent error. Physical barriers, such as locking a patient controlled analgesia device, are the strongest but are not possible for every situation. Natural barriers are temporal, for example, waiting between two independent brain stem deaths tests, or distance placement barriers, for example, locking potassium solution for i.v. injection away with controlled drugs. Checking blood before transfusion is an example of a human action barrier. Administrative barriers include protocols, supervision and training. Human and administrative barriers are weak as they are particularly prone to error.

iv. Recommendations and implementation: RCA is performed by a team of clinicians, risk managers and sometimes lay-people involved in the PSI. A single sentinel event such as a catastrophic PSI should always trigger the commissioning of a RCA. Common RCA findings include communication failure and insufficient education and training.

PROSPECTIVE IDENTIFICATION

This is again closely related to the day-to-day work of an anaesthetist. Planning an anaesthetic, equipments needed, staffs required represents prospective risk assessment. Think of how we would plan to transfer an ICU patient to the CT scanner. It should be kept in mind that safest place for the patient to recover is the operation theatre itself, since all necessary equipments and drugs are close-by for access in the event of any mishap[21] and all the intensive care given to the patient during intraoperative period is only to be abandoned in the immediate post-operative period, hence, should not be in a hurry to shift[22]. It can also be a systematic and comprehensive review of a whole organization looking for potential risks which usually involve a risk management team formed from a variety of professional backgrounds from each department. Broad areas of risk such as "equipments" are analysed and, for each category, key questions are asked, for example, do staff know how to operate this equipment? How do we know they know? Have they been assessed as competent? Do they know what to do if the equipment fails? Conducting such a review has become increasingly common as it is one of the criteria that must be fulfilled in order to demonstrate compliance with the Clinical Negligence Scheme for Trusts (CNST) risk management standards administered by the NHS Litigation Authority. Information gathered should include the nature of the risk, current barriers to the hazard and suggestions about how the risk could be managed.

RISK ASSESSMENT AND ANALYSIS

Once a particular risk has been identified, the magnitude of the risk needs to be assessed to determine the extent and nature of the control measures required to bring the risk within acceptable levels. Two aspects of the risk are assessed: the likelihood of occurrence or recurrence; and the most likely outcome should the hazard be realized. A commonly used scale for outcome severity is as follows:

I None, no adverse clinical outcome or a prevented PSI;
ii. Minor, short term injury taking up to a month to resolve;
iii. Moderate, a semi-permanent injury that may take up to 1 yr to resolve;
iv. Major causing permanent disability;
v. Catastrophic, resulting in death.

Alternative ways of estimating severity are the number of patients involved and the likely cost of litigation. Frequency of occurrence can be assessed using the scale as follows:

i. Almost certain, and likely to occur on many occasions;
ii. Likely, an outcome that is expected to occur;
iii. Possible, an outcome not expected to occur;
iv. Unlikely, an event that may occur in a large organization on a less than annual basis;
v. Rare, an event that a clinician would probably not see in his/her career.

Severity and frequency of the most likely outcome can then be combined in a matrix and the position of each risk on the matrix assigned an overall risk

rating or numerical value. For elective patients returning to understaffed wards at night (example 1), it could be said that the most severe outcome would be that a preventable catastrophic complication was not being referred to medical staff in time and assigned “high risk”. However, the most likely outcome is that the patient receives inadequate analgesia, a minor consequence as it will be resolved when staffing levels improve in the day. Although this will almost certainly happen, the overall classification is of “low risk”. In example 2, for a junior obstetric anaesthetist, unsupervised in a remote location, the most likely consequence resulting from the location is likely to be more serious, for example, mismanagement of major haemorrhage. However, this is less common than example 1 and is classified “moderate risk”. In example 3, for new trainees not knowing the location of the difficult airway equipment, it could be argued that the most likely outcome is failure to oxygenate adequately, and the potential catastrophic outcome makes it “high risk”, even after considering the probability of the event. The numbers for frequency and severity can be multiplied to give an overall score, or risks can be ranked by a traffic light system of colour from the matrix. At institution level, the ranked risks are held in a risk register so as to prioritize limited resources to reduce risk appropriately.

RISK MANAGEMENT

The anaesthesia related risks can be significantly reduced by routine anaesthetic machine checks, syringe labeling, appropriate supervision of trainees and assistants, and competency assessment of anaesthetists to ensure they are capable of performing to the required level. Training has traditionally been focused towards clinical activity but the general principle of risk awareness should be formally established in anaesthetic training from the beginning. Anaesthesia is terribly simple, but at times, can be simply terrible[23]. Death due to disease may be inevitable but death due to anaesthesia is a tragedy. There are no safe drugs or techniques but there are only “safe” or “unsafe” anaesthetists[24]. Medications error is not usually caused by 'bad' practitioners, but are almost inevitably the result of system failures coupled with the failure of cognitive strategies employed by anesthetists. Hence, an anaesthetist should always be prepared to face the unexpected and be alert throughout the peri-operative period. Commonsense says, a reasonable amount of sleep and rest is necessary before taking up a patients's life into own hands.

The actions are taken aim to reduce an identified hazard to a tolerable risk, that is, a risk that has been reduced to the lowest level possible within available resources. A hierarchy of control methods exists from no action to complete removal of a particular risk. As mentioned previously, a physical barrier is one of the most robust methods of risk reduction, for example, a locked drug cupboard. However, there are very rarely absolute physical barriers in place; for example, it is difficult to make it impossible to administer an incorrect drug to a patient (although this has been suggested in the case of intrathecal administration by using a unique syringe connector), and we usually rely on imperfect barriers such as syringe labeling. Hence, “5 rights” of medication should be followed during drug administration- “right patient/ right drug/ right dose/ right time/ right route”. A technique known as a “hard stop” has been initiated, so that any healthcare professional in an operating room or beyond, including the technicians and nurses, can call for an immediate cessation of all activities and a quick discussion and evaluation of the process if they believe harm could result to the patient[13]. After a mishap, a brief discussion should be initiated, of those involved (a huddle) held the next day in the operating room before the cases start or a more lengthy process that investigates the entire system (root cause analysis). Lower down

the hierarchy are policies and protocols to promote safe working practices and education and training, for example, the Minimal Mandatory Monitoring Guidelines[26] that have been almost universally followed in anaesthesia in the developed world. Although there is no level 1 evidence that this has affected mortality, it is generally considered that the benefits are beyond doubt and that such a trial would be unethical.

The training, and possibly selection, of staff is a target for risk management. The level of supervision of trainees in anaesthesia is also clearly linked with clinical risk. There is inevitably a learning curve in any area of anaesthetic practice and the assessment of the appropriate levels of competence for various levels of supervision is becoming an increasingly prominent part of anaesthetic training. Competence is a point on a spectrum of ability from absolute beginner to expert. Deciding what competence is and how it should be assessed is subjective and often open to debate, balancing what is an acceptable level of risk to the patient within the resource limitations. Ultimately, dealing with risks involves managing uncertainty, especially if assessing risks prospectively.

RE-EVALUATION

Risks should be regularly reviewed and reassessed to ensure the assessments remain accurate and new risks have not been introduced by controls intended to reduce risk. Any new practice, service activity or procedure should prompt a clinical risk assessment to ensure appropriate controls and salvage strategies are implemented.

As discussed, anaesthetists have pioneered many system-based initiatives to reduce avoidable harm to patients, largely through addressing the problem of human error. Perrow and Reason have been influential in informing the adoption by anaesthetists of the concepts of systems thinking, incident reporting, and root-cause analysis[27]. It is now recognized that errors are inevitable in systems such as healthcare, because of complexity and the latent factors that setup humans to fail. These errors may occur in technique, judgement or simply due to failure of vigilance. Accidents are funny things which might not be know that they are happening until they happen[28]. So, it is apt and appropriately said that “eternal vigilance” is the price of “safety”[29]. Emphasis on a 'blame-free culture' has given way to the concept of a 'just-blame culture', but in either case practitioners need to feel safe to report their errors, knowing that the aim is to improve safety rather than to blame individuals, to ensure that the causes of the event are identified so that a recurrence can be prevented. If we can't undertake a clinical responsibility with a proper safety, the only honest and forthright attitude must be not to undertake it[30]. Success has no meaning without “safety” in clinical practice. Patients place their “trust” on us and we are responsible for ensuring their “safety”, professionally, morally and legally.

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BASKA MASK AIRWAY: A NOVEL SUPRAGLOTTIC AIRWAY

Chavi Sarabpreet Sharma[1], Aanchal Kakkar[2], Manpreet Singh[3]

The introduction of Archie Brain's LMA-Classic into clinical practice in 1988[1] brought about a revolution in anesthesia. Since then there has been a plethora a new extraglottic airway devices (EAD).

The Baska mask is a novel supraglottic airway device, designed by Australian anesthetists Kang and Meena Baska, is a new CE approved and internationally patented EAD, provided in single use and multiple-use versions[2,3]. The Baska airway brings together features of:

1) LMA-Proseal i.e. high pressure, gastric access port and bite block, which facilitate ventilation, provide airway protection, and minimize airway obstruction.

2) LMA-Supreme i.e. oval shaped, anatomically curved airway which incorporates gastric drain tube.

3) I-gel – Self inflatable balloon

4) Slipa-Cuffless, anatomically pre-shaped sealer with a sump reservoir.

Performance data suggest that it is feasible to obtain adequate or good outcomes with a high first attempt success rate (88%), Easy insertion (92%), short insertion time (16 secs) and effective airway time (32 secs)[2-4].

The Baska mask is another step forward in search for an ideal extraglottic airway device (Fig. 1, 2),

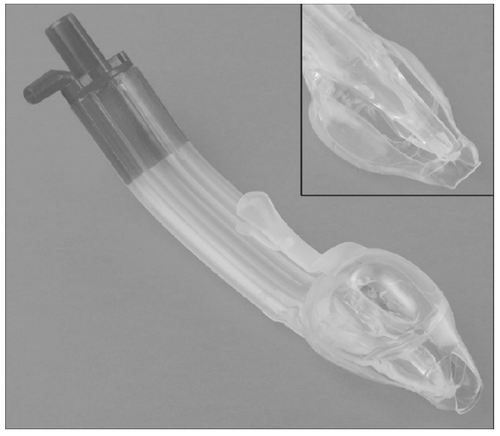

Fig. 1: Bask mask

Authors 1,2= Department of Anaesthesia and Critical Care, UCMS and GTB Hospital, Dilshad Garden,India
Author 3: Department Of Anaesthesia and Intensive Care, Govt. Medical College and Hospital,
Sector 32, Chandigarh, India

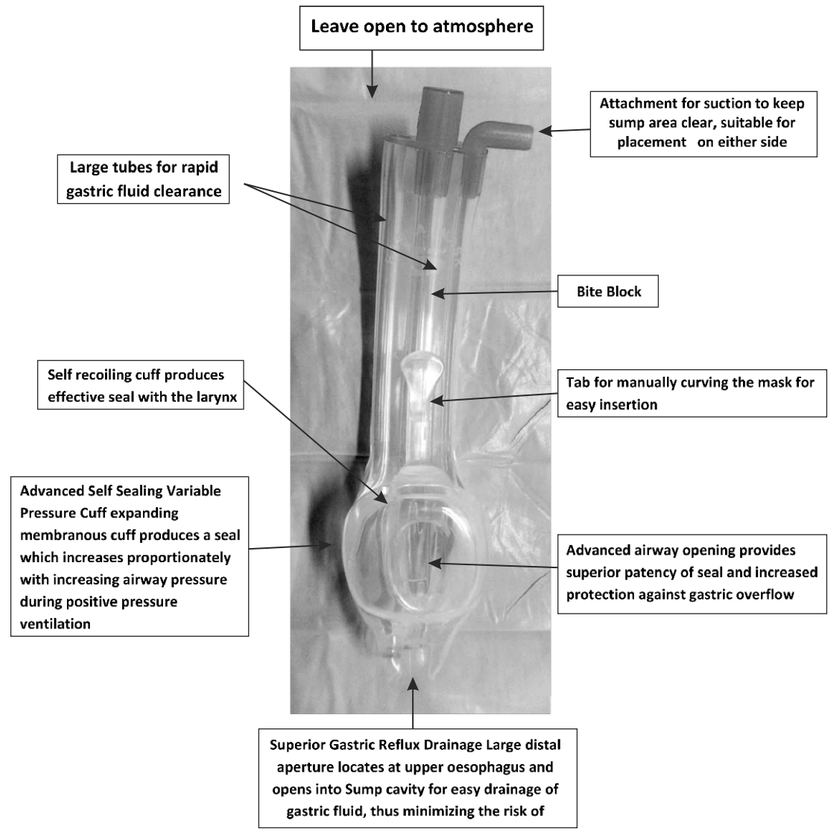

Fig. 2: Special features of Baska Mask

which incorporates an airway tube, a tab to help negotiate the paloto-pharyngeal curve, two large sump reservoir to collect any fluid entering the pharynx.

The self-recoiling membrane distally open cuff silicone mask consists of an anatomically curved airway tube with: (a) bite block over the full length of the airway, (b) Self-sealing membranous variable-pressure cuff which adjusts to the contours of the mouth and pharynx, (c) a large sump cavity with a two aspiratable gastric drain tubes, (d) a tab for manually curving the mask to ease insertion, and (e) suction elbow integral to one port with a second port acting as a free air flow access.

Cuff of baska mask is not an inflatable balloon, but a membrane which inflates on every breath during IPPV to achieve a superior seal when opposed to larynx.

Achieve a superior seal when opposed to larynx.

Baska mask cuff looks larger than standard first generation laryngeal mask airways contrary to other EADs, the baska mask cuff can easily be decreased in size by compressing the proximal, firmer part of mask between thumb and fingers making insertion easier. As there is no inflated cuff in baska mask neither should it cause tissue or nerve damage nor should the intracuff pressure need monitoring.

Both spontaneous and IPPV are possible with baska. Single use baska mask are available but manufacture (PROCAT Medical system, Frenchs, Forest NSW, Australia) also provide multiple use version, which can be used 70 times.An oropharyngeal leak pressure of >30 cmH_2O was obtained with all baska mask, whereas ¾ of the patient had maximum pressure of 40 cm H_2O which is typical for second generation EADs[5-10] and much higher than 1st generation LMA Classic. Fiberoptic evaluation of anatomic position of Baska mask in situ, revealed that 54% of patient showed perfect position of vocal cords, whereas in 12 % epiglottis was visible[11,12](Fig. 3).

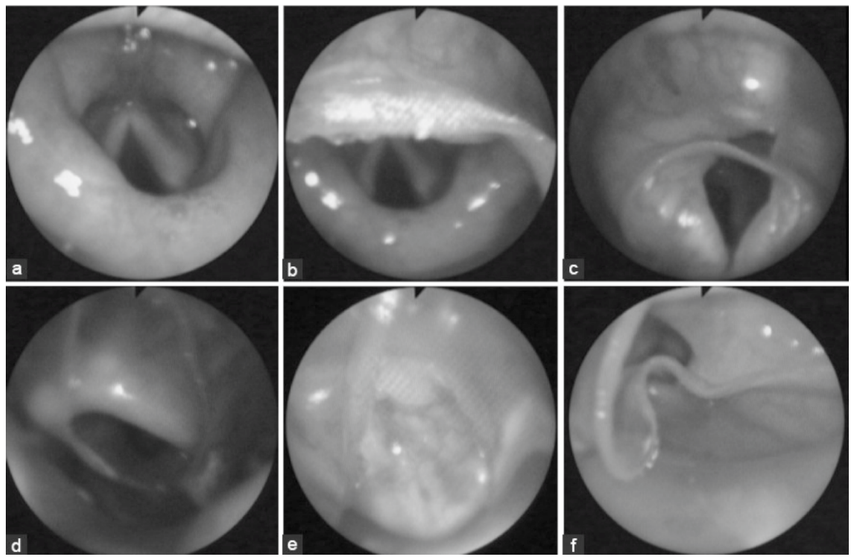

Fig. 3: Fibreoptic view

The soft membranous part of cuff is wrinkled around epiglottis. Studies revealed that learning curve for this is very short, although additional studies are required to explore the learning curve in more detail[12,13].The relatively low complication rate and absence of serious complication are encouraging.

We conclude that baska mask demonstrates a level of utility as an alternative supraglottic airway that is worthy of further clinical study, and the present invention encompasses all such variations and modification that fall within its spirit and scope.

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