

Extraglottic Airways in Tactical Combat Casualty Care

TCCC Guidelines Change 17- 01

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Abstract

Extraglottic airway (EGA) devices have been used by both physicians and prehospital providers for several decades. The original TCCC Guidelines published in 1996 included a recommendation to use the laryngeal mask airway (LMA) as an option to assist in securing the airway in Tactical Evacuation (TACEVAC) phase of care.

A variety of EGAs have been used in combat casualty care over the past 20 years. In 2012, the Committee on TCCC (CoTCCC) and the Defense Health Board (DHB) reaffirmed support for the use of supraglottic airway (SGA) devices in the TACEVAC phase of TCCC, but did not recommend a specific SGA based on the evidence available at that point in time. This paper will use the more inclusive term “extraglottic airway” instead of the term “supraglottic airway” used in the DHB memo.

Current evidence suggests that the i-gel EGA performs as well or better than the other EGAs available and has other advantages in ease of training, size and weight, cost, safety, and simplicity of use. The gel-filled cuff in the i-gel both eliminates the need for cuff pressure monitoring during flight and reduces the risk of pressure-induced neuropraxia to cranial nerves in the oropharynx as a complication of EGA use. The i-gel thus makes the medic’s tasks simpler and frees him or her from the requirement to carry a cuff manometer as part of the medical kit.

This latest change to the TCCC Guidelines as described below does the following things:

- 1) Adds extraglottic airways (EGAs) as an option for airway management in Tactical Field Care;
- 2) Recommends the i-gel as the preferred EGA in TCCC because its gel-filled cuff makes it simpler to use than EGAs with air-filled cuffs and also eliminates the need for monitoring of cuff pressure;
- 3) Notes that should an EGA with an air-filled cuff be used, the pressure in the cuff must be monitored, especially during and after changes in altitude during casualty transport;
- 4) Emphasizes COL Bob Mabry's often-made point that extraglottic airways will not be tolerated by a casualty unless he or she is deeply unconscious and notes that an NPA is a better option if there is doubt about whether or not the casualty will tolerate an EGA;
- 5) Adds the use of suction as an adjunct to airway management when available and appropriate (i.e., when needed to remove blood and vomitus);
- 6) Clarifies the wording regarding cervical spine stabilization to emphasize that it is not needed for casualties who have sustained only penetrating trauma (without blunt force trauma);
- 7) Reinforces that surgical cricothyroidotomies should not be performed simply because a casualty is unconscious;
- 8) Provides a reminder that, for casualties with facial trauma or facial burns with suspected inhalation injury, neither NPAs nor EGAs may be adequate for airway management, and a surgical cricothyroidotomy may be required;
- 9) Adds that pulse oximetry monitoring is a useful adjunct to assess airway patency and that capnography should also be used in the TACEVAC phase of care; and
- 10) Reinforces that a casualty's airway status may change over time and that he or she should be frequently re-assessed.

Key Words: Extraglottic airway, i-gel, TCCC, Tactical Combat Casualty Care

Proximate Reasons for This Change

The Joint Trauma System (JTS) has been designated by Congress as the Lead Agency for trauma care in the Department of Defense (DoD). In that capacity, the JTS forwards recommendations about best-practice, evidence-based trauma care to the four US Armed Services and to the US Military Combatant Commands. The Committee on Tactical Combat Casualty Care (CoTCCC) is the prehospital component of the JTS.

In the interval since the last airway change to the TCCC Guidelines in 2012, a number of developments have resulted in the need for this change:

- 1) The use of EGAs has expanded rapidly in the civilian sector – in prehospital care, in the Emergency Department, and in the operating room. EGAs are easy to insert and have proven very effective. (1-18)
- 2) In the JTS weekly trauma teleconferences, combat medics have been observed to perform surgical airways on a number of occasions for casualties who were unconscious from hemorrhagic shock or traumatic brain injury (TBI), but who had no direct maxillofacial injuries or documented airway problems. In unconscious casualties without an observed airway obstruction, EGA use should be attempted to manage the airway before undertaking a surgical airway.
- 3) In individuals who are unconscious from hemorrhagic shock or TBI, but who do not have direct trauma to airway structures, the only airway interventions other than surgical airways recommended in the TCCC Guidelines for use during Tactical Field Care (TFC) have been the chin-lift, jaw-thrust maneuver, nasopharyngeal airways (NPAs), and the use of the recovery position. Although intracranial insertion of NPAs is rare and has not, to the authors' knowledge, occurred in US casualties from Iraq and Afghanistan, it has been reported in the literature. (19-23) EGAs do not entail the risk of intracranial placement and are an important, safe, and easy-to-use item that can be added to the combat medic's kit to help manage the airway during TFC.
- 4) The i-gel was introduced in 2007 and has a number of characteristics that make it favorable for use on the battlefield. Notably, the cuff that fits over the laryngeal inlet is filled with a soft gel rather than air. This feature has 4 advantages on the battlefield: 1) the combat medical provider does not have to carry a syringe for the purpose of inflating the cuff; 2) not having to fill the cuff with air saves the medic, corpsman, or PJ from having to take the time required for that action during airway insertion; 3) the gel does not expand at altitude during evacuation on aircraft, as air-filled cuffs do, thus making it unnecessary to monitor EGA cuff pressure during air transport; and 4) the lack of increased cuff pressure relative in the EGA cuff relative to ambient lowers the potential for iatrogenic damage to neural structures in the oropharynx secondary to EGA use.
- 5) The emerging literature has shown the i-gel EGA to be as good or better than other EGAs in multiple studies. (5,10,13,24-30)

6) Overpressurization of EGA cuffs is associated with palsies of the cranial nerves that pass through the oropharynx. (31-34) This can occur even without a change in ambient pressure, but the decrease in atmospheric pressure associated with helicopter transport of combat casualties results in increasing relative pressure inside the volume-limited EGA cuff and an increased risk of barotraumatic neuropraxia. A study done on a Combat Casualty Aeromedical Transport Team (CCATT) training mission that examined 4 methods of managing cuff pressures during flight concluded that none were satisfactory and that new technology or techniques need to be developed. (35) The i-gel has a gel-filled cuff that does not increase in volume or cause elevated cuff pressures at altitude. This lowers the potential for cuff overpressurization and resultant cranial nerve palsies.

7) The i-gel was found to be the fastest EGA to insert in individuals who are wearing chemical, biological, radiation, nuclear-personal protective equipment (CBRN-PPE). (36)

Background

Airway obstruction was the second leading cause of preventable death in the prehospital phase of care for US combat fatalities during the conflicts in Iraq and Afghanistan, (37) thus emphasizing the need for combat medical personnel to be proficient in managing casualties with airway injuries on the battlefield.

Extraglottic Airways

The esophageal obturator airway (EOA) was developed in the 1970's and included a large tube with a balloon that occluded the esophagus and a mask attached to the tube that had an opening to allow for ventilation. As the patient was ventilated via bag-valve-mask (BVM), air could only go into the trachea since the esophagus was occluded. (38) The EOA had too many moving parts and some major complications such as tracheal occlusion and esophageal perforation. It never became popular in emergency departments, although many EMS units used them. One of the skills required for an emergency physician in the past was the ability to tracheally intubate a patient with an EOA in place.

The first extraglottic airway (EGA) was invented by Archie Brain in 1981 and became commercially available in the United States in 1991. It was called the laryngeal mask airway (LMA) and became widely used in anesthesia and prehospital care. The LMA was designed to provide ventilation while positioned above the glottis with an inflated mask that seals the esophagus, allowing for air to enter the trachea. Currently there are

many similar devices that use the same principle and attempt to improve on the ease of placement and protection from aspiration while still providing oxygenation and ventilation. Several articles have discussed the advantages of the EGA over endotracheal intubation in the operating room (OR) and these advantages, especially the ease of insertion and training, also make EGAs an ideal airway for pre-hospital use. (12,39,40) The EGA is now routinely used in the OR, emergency department (ED), and prehospital practice as a routine airway device as well as a rescue and difficult airway device. (2-4,7, 8-13,15,17,18)

The 1996 TCCC Guidelines included a recommendation to use the LMA as an option to assist in securing the airway in the Tactical Evacuation (TACEVAC) phase of care. A variety of EGAs have subsequently been used in combat casualty care over the past 20 years. The US Army has used the King LT EGA during the conflicts in Iraq and Afghanistan (41) after a study by McManus et al showed this device to be quickly and easily placed by combat medics. (42) Adams and his co-authors further noted that “In the combat setting, medical direction in far-forward Army units is not standardized and training can vary widely between units and individuals....” (41)

In May of 2012 one of the authors (EJO) presented evidence to the CoTCCC that other SGAs were similar to the LMA with respect to training time, efficiency of ventilation, speed of insertion, and complications. The CoTCCC and the Defense Health Board (DHB) subsequently reaffirmed support for the use of SGAs in the TACEVAC phase of TCCC, but changed the recommendation from the LMA to a generic SGA recommendation based on the available evidence at that point in time. (43) Note that this paper will use the alternate term extraglottic airway (EGA) instead of the term SGA that was used in the DHB memo in order to be more anatomically precise about the location of the device.

The DHB went on to recommend that if an EGA device was found to be superior to other options based on the best available evidence, then that device should be standardized across the military Services. (43) The evaluation criteria that is used to guide decisions regarding a particular item of combat casualty care equipment as evaluated by the CoTCCC New Technology Subcommittee consists of the following: 1) it works - based on the available evidence; 2) easy to apply/use; 3) easy to train; 4) rapid insertion/time efficient; 5) minimal complication rate; 6) small packaging; 7) long shelf life; 8) suitable for all environments; 9) common accessories (batteries, plugs, accessories); 10) minimal risk; and 11) low cost.

The insertion of EGAs is relatively easily mastered. Studer and his co-authors studied 28 predeployment soldiers who volunteered to undergo Combat Lifesaver training. None had had previous experience with the King LT-D device used for the study. The students received 20 minutes of PowerPoint instruction followed by a practical session (unlimited time) on a training manikin. They were then timed during an insertion attempt. 27 of 28 students were able to successfully place a King LT-D airway device in under 60 seconds following this brief training session. (12)

Discussion

The Evidence against Prehospital Endotracheal Intubation in Trauma

For many years, endotracheal intubation (ETI) was the “Gold Standard” for definitive airway management in both the prehospital and hospital environment. Even in studies that do not entail injuries to airway anatomy, however, the success rate for ETI in trauma patients when performed by individuals who do not have a strong training and experience base in this procedure is poor. (44, 45) As one author noted, “...it was difficult to secure time when paramedic students could practice their intubation skills on live patients. In actuality, many paramedics of that era were graduated without ever having the opportunity to perform an ETI on a living patient.” (46)

Other reports have questioned the use of ETI in the prehospital management of trauma patients due to high failure rates secondary to training issues, relative lack of experience of the provider, lack of sedation and paralysis, and/or the resource-limited prehospital environment. (47-49) Additionally, even when ETI is performed successfully, several studies have documented worsened outcomes in trauma patients whose airway was managed with ETI. (50) In a study of matched cohorts of 8139 isolated severe blunt TBI patients with and without prehospital ETI, prehospital ETI was associated with significantly longer transport times (median 26 vs 19 min, $p < 0.001$) and increased mortality (OR 1.399, CI 1.205/1.624, $p < 0.001$). (50)

Further, most airway fatalities in combat casualties are associated with direct trauma to the airway structures (51) and there is no evidence that documents that combat medical personnel can reliably perform ETI in casualties with maxillofacial trauma. (45) This is especially true if the medic is not prepared to perform Rapid Sequence Intubation (RSI). The first preventable death analysis performed on US casualties from the conflicts in Iraq and Afghanistan noted a fatality that occurred because of a failed attempt at ETI in a casualty with maxillofacial trauma and airway obstruction. (52)

The LMA was recently reported to be useful as a rescue airway for combat casualties being transported by helicopter when endotracheal intubation had failed. Sixty-five casualties were reported; 47 were successfully intubated. Of the 18 casualties in whom intubation failed, 16 of the 18 subsequently had an LMA placed successfully. (1)

The Evidence for Prehospital EGAs in Unconscious Patients without Facial Trauma

EGAs have replaced ETI for many surgical procedures, in emergency departments, and in the civilian prehospital community. (1-18) As noted above, they are also used as rescue airways after failed ETI attempts. EGAs have several advantages over ETI:

- ease and speed of insertion;
- decreased risk of harm from malposition;
- improved ventilation when compared with BVM alone;
- less training and experience required for successful application than ETI; and
- no need for laryngoscopy.

EGA use produced a higher success rate than ETI, both during the initial training session and after a 3-month interval. (44) The King LT is the current EGA that the US Army is training and equipping for 68W combat medics. This EGA had a higher first attempt insertion rate than ETI in a study of 351 prehospital cardiac arrest patients (87.8% vs. 57.6%) (53) The i-gel EGA, when used to secure the airway in prehospital non-traumatic cardiac arrest patients, had a 90% successful insertion rate on the first attempt by paramedics and emergency physicians, with an additional 7% being successful on the second attempt, and remaining 3% successful on the third attempt. (10) Four different EGAs were able to be inserted by 141 lay persons with a success rate greater than 95% after only 30 minutes of training. (54) The authors of this study recommended the addition of EGAs to first aid and BLS algorithms. The King LT was also found to be faster to place than an endotracheal tube in a manikin study where the manikins were wearing personal protective equipment designed for hazardous conditions. (55)

Avoidance of Cuff Overpressure-Related Complication with EGAs

Neural Injuries are an uncommon complication of EGA use, but have been reported. Nerves at risk include branches of the trigeminal, glossopharyngeal, vagus and hypoglossal nerves. (31, 56-58) One review of this topic found that the lingual nerve was the most commonly affected (22 patients). Other nerves injured by EGAs included the recurrent laryngeal (17 patients), the hypoglossal (11 patients), the glossopharyngeal (3 patients), the inferior alveolar (2 patients) and the infra-orbital (1 patient). (31) Contributing factors may include: an inappropriately sized EGA; misplacement of the device; patient positioning; overinflation of the device's air-filled cuff; and poor insertion technique. Injuries other than to the recurrent laryngeal nerve are usually mild and self-limiting. Understanding the diverse presentation of cranial nerve injuries helps to distinguish them from other complications and assists in their management. (31)

Nerve injuries associated with EGA use are typically caused by pressure neuropraxia. (31-34) This may be due to overpressurization of air-filled EGA cuffs. Overpressurization may occur with a change in ambient pressure (as with ascent to altitude) or as a result of overinflation of the cuff. (31) One case report noted a transient vocal cord palsy following the use of an LMA. In this case, the development of inappropriately high cuff pressure secondary to nitrous oxide diffusion during anesthesia was proposed as the most likely cause of this injury and the authors of that report

proposed mandatory monitoring of the intraoperative cuff pressure during anesthesia to lower the risk of such injuries. (34) Another case report described a patient who experienced temporary bilateral vocal cord palsy after a surgical procedure in which an LMA was used. That paper noted that “the most widely accepted mechanism of recurrent laryngeal nerve injury is pressure neuropraxia secondary to nitrous oxide diffusion into the cuff.” (32) Although most of these incidents of EGA-induced neuropraxia are temporary, vocal cord paralysis from recurrent laryngeal nerve damage may be permanent. (58)

The decrease in atmospheric pressure associated with helicopter transport of combat casualties results in increasing pressure inside the volume-limited EGA cuff and an increased risk of barotraumatic neuropraxia. Studies of air-filled endotracheal tube (ETT) cuffs have found that cuffs inflated before air transport are likely to exceed critical pressure levels rapidly during flight. (59,60) Further, if the EGA is inserted at altitude, there will be a loss of cuff pressure during descent, with a resultant loss of good seal. (59) This results in recommendations for frequent monitoring and management of air-filled cuff pressures during ascent and descent. (59,60) The need for repeated checks of cuff pressure is eliminated if the EGA used has a cuff filled with a liquid rather than air, since liquids do not expand at reduced ambient pressures (61), but using water or saline solution to fill airway cuffs designed to be inflated with air is not allowed by the Air Force Instruction that provides guidance for care provided at altitude. (62) US Air Force guidance for managing endotracheal and tracheostomy tubes states that “8.4.8.3.1: Cuff pressure is usually maintained between 15-20 cm, and will be checked preflight, at cruise altitude, hourly, on descent, and prior to deplaning. Document cuff pressures on patient’s medical record.” This Air Force Instruction also states that: “8.4.8.3.2: If an ERCC team is unavailable and an ETT or tracheostomy tube cuff requires inflation for flight, ensure it is inflated with air. Use minimal occlusion volume/minimal leak technique in an effort to permit adequate ventilation and avoid tissue trauma. WARNING: Excessive pressure in the endotracheal or tracheostomy cuffs may decrease blood flow to tissue causing airway damage, while underinflation may permit air leak/ineffective ventilation and increased potential for aspiration of upper airway secretions.” (62) EGAs are not specifically addressed in this instruction, but would presumably also require filling with air and hourly monitoring.

One study done by C-STARS in Cincinnati monitored ETT cuff pressures during a CCATT training flight to 8000 ft cabin pressure to study the issue of overinflation in ETT cuffs at altitude in order to help prevent mucosal injury. The ETTs were placed in a tracheal model while mechanical ventilation was being performed. The control ETT cuff was inflated to 20-22 mmHg and was not manipulated. Another cuff was managed manually using a pressure manometer to adjust pressure varying altitudes. For the third tube, a “PressureEasy” device was employed and set to a pressure of 20-22 mmHg. The fourth cuff was filled with 10 mL of saline. The study found that, in the control ETT tube cuff, pressure exceeded 70 mm Hg at 8000 ft. The cuff managed manually was corrected for pressure at altitude, but recorded low cuff pressures at landing (<10 mm Hg). The PressureEasy device reduced the pressure at altitude to a maximum of 36 mmHg, but cuff pressure was less than 15 mm Hg at landing. The saline inflation

eliminated cuff pressure changes at altitude, but the initial cuff pressure was 40 mmHg. The authors concluded that “None of the three methods using air inflation managed to maintain cuff pressures below those associated with tracheal damage at altitude or above pressures associated with secretion aspiration during descent. Saline inflation minimizes altitude-related alteration in cuff pressure but creates excessive pressures at sea level. New techniques need to be developed.” (35)

The i-gel as the EGA of Choice in TCCC

There are now approximately 30 EGAs available in the marketplace. (63) Most of these use inflatable cuffs to occlude the esophagus. The i-gel (Intersurgical, Wokingham, Berkshire, UK) does not use an inflatable cuff, but rather is made of a gel-like thermoplastic elastomer that conforms to the anatomy of the hypopharynx. The i-gel comes in seven sizes for both adult and pediatric usage and has gastric access and oxygen delivery components. The emerging literature has shown the i-gel EGA to be a good option for managing the airway, both when studied alone or in comparison to other EGAs. (5,10,13,16,24-30,64)

In evaluating the various EGA devices, the New Technology Subcommittee of the CoTCCC took into account a number of additional qualities that were believed to be relevant to battlefield use of an EGA. These included size and weight, training for entry level medics, sustainment of skills, environmental engineering factors, cost, and durability. The device must be robust and easy to use in any weather conditions as well as at various altitudes and temperatures. It must have few parts that are necessary for its deployment; be lightweight; have minimal cubic size; be inexpensive; and be easy to train in its application. In addition, to address various battlefield contingencies, the EGA should be able to be inserted in both the supine and the prone positions as well as other casualty positions. (25,65)

In an Armed Forces Medical Examiner System (AFMES) “Feedback to the Field” case series, of 7 military postmortem cases in whom the King-LT was used, 4 were incorrectly positioned. (43) It is important to note that the position of the device as noted at autopsy may have been affected by post-mortem handling of the body. The i-gel is associated with a very low rate of dislodgement, and is easy to position correctly.

Other favorable aspects of the i-gel include:

- Has a gastric tube port
- Has an oxygen port
- Provides easy access for fiberoptic intubation
- Is associated with very little aspiration
- Is popular with civilian anesthesiologists, paramedics, and emergency physicians
- Is widely used in European ambulance services
- Has a gel-filled cuff, not a balloon

- Is simpler to use than other EGAs
- Can be inserted with the patient in prone position
- Is easily trained
- Can be used in any environment or altitude
- Costs about half of what other EGAs cost
- Has a 3-year shelf life
- Can be tolerated by conscious casualties after ketamine administration
- Comes in a smaller package than other EGAs
- Does not require in-flight monitoring of cuff pressure

(7,18,36,44,46,54,55,66)

There is increasing evidence in the medical literature that the i-gel performs well in comparison to other EGAs. (4,5,10,13,17,25,26,29,30,64-66,68) The i-gel has been found to perform well as an airway option in elective surgery patients.

(2,5,6,16,24,27,68,69) The i-gel was also found to be easily inserted in manikins who were in the prone position. (25,65) The i-gel was found to be a suitable alternative to ETI for surgical patients in the laparoscopic pneumoperitoneum and Trendelenburg position. (68) In a prospective, controlled, randomized trial, in 80 anesthetized elective surgery patients, the insertion success rate was higher in the i-gel group (100% on the first attempt) than in the Proseal-LMA group (82.5% on the first attempt). The mean insertion time for the i-gel group was significantly faster than that of the Proseal-LMA group (i-gel: 8±3 seconds vs P-LMA: 13±5 seconds). The airway leakage pressures were similar. The authors concluded that the i-gel was the preferred EGA between the two. (5)

Another randomized, single-blind, controlled study with 64 anaesthetized and paralyzed patients compared the i-gel and the LMA-Classic. Successful insertion time was significantly shorter for the i-gel. (27) Joly and co-authors conducted a prospective randomized study of the i-gel vs the LMA-Supreme in 100 elective surgery patients who had procedures done under general anesthesia. Both EGAs were inserted successfully in 92% of patients. The authors found no significant difference in the leak pressures between the two devices. The insertion time was shorter with the i-gel (19 sec) than with the LMA Supreme (27 sec) and the vocal cords were completely visualized in 70% of i-gel patients in contrast to 50% of LMA Supreme patients. (69) In a large 2012 study of 2049 i-gel uses in the operating room, the overall success rate was 96%. I-gel insertion was deemed “very easy or easy” in 92% of patients. (16) The authors concluded that: “The i-gel is a reliable supraglottic airway device failing in <5% and providing high airway leak pressures. Males, impaired mandibular subluxation, poor dentition, and older age are risk factors associated with primary device failure. Serious adverse events are rare.” (16)

A 2012 prospective, randomized trial studied two group of spontaneously breathing patients who had a variety of surgical procedures performed under general anesthesia. The i-gel was used for forty patients and the LMA Classic was used for another group of 40. The insertion of the i-gel was significantly faster (15.6 sec) as compared to 26.2 for the LMA Classic. The leak pressure was also found to be higher for the i-gel. (28)

Jaoua's 2014 study of 100 elective surgery patients undergoing general anesthesia found a successful i-gel insertion rate of 99%. The device was able to be inserted on the first attempt in 92% of cases and the i-gel was rated as easy to use in 99% of cases. The median insertion time was 13 seconds. The conclusion from the study was that the i-gel "can be used safely and effectively in patients undergoing short-duration elective surgery because the i-gel has a very good insertion success rate and few complications." (6)

The study by Russo et al examined the i-gel, the LMA Supreme, and the Laryngeal Tube Suction-D in elective surgery patients with groups of 40 patients each. The insertion success rate for the i-gel and the LMA-Supreme were both reported as 95%, while the LTS-D had a success rate of 70%. (17) An Australian study comparing the i-gel with the Portex Soft Seal Laryngeal Mask (PSS-LM) in patients who had suffered an out-of-hospital cardiac arrest. Fifty-one patients were randomized for this study. The insertion success rate was 90% for the i-gel as compared to 57% for the PSS-LM. (67) Although one cadaver study found that the i-gel had a lower leak pressure than the Proseal LMA and the LMA Classic, (70) a larger study by Polat in 2015 also compared the i-gel and the LMA-Classic and found regurgitation not to be a problem. This study had groups of 60 patients for each of the two devices. The findings from that study were similar to the Atef study mentioned previously. Both devices were reported to perform well without incidents of regurgitation. (71) The Polat study also found that the i-gel had a shorter insertion time and a better fiberoptic view than the LMA Classic. (71) In a study designed to examine the use of EGAs in casualties wearing chemical/Biological/Radiological/Nuclear (CBRN) protective equipment, the i-gel was found to have the shortest insertion time of the EGAs tested. (36)

Four studies have noted that the LMA Supreme performed well in comparison to other EGAs. (17,29,72,73) In a study of military novices comparing 5 different EGAs, the LMA Supreme first-attempt success rate was 95% as compared to the i-gel first attempt success rate of 87%, although the final success rate for both devices was 99%. The insertion time for the i-gel was 74 seconds as compared to the LMA Supreme's 70 seconds. Thirty-seven percent of study participants rated the i-gel as 'very easy to insert' vs 61% for the LMA Supreme. The authors concluded that: "Most study parameters for the Supreme LMA and i-gel were found to be superior to the other three tested supraglottic airway devices when inserted by military novices." (29) The 2012 Ragazzi study used airway novices who were randomly assigned to use the LMA Supreme or the i-gel in 80 patients who were undergoing breast surgery. The first-attempt insertion success rate was significantly higher for the LMA Supreme device (77%) than for the i-gel (54%); $p = 0.029$. There were significantly more insertion failures with the i-gel (6) vs none with the LMA Supreme. ($p = 0.025$). This study noted that more patients complained of pharyngolaryngeal pain with the LMA Supreme (44%) than with the i-gel (20%); $p = 0.053$. The authors concluded that "We found better first time success rate, fewer failures, and a better seal with the LMA Supreme compared with the i-gel, indicating that the LMA Supreme may be preferable for emergency airway use by novices." (73)

The LMA-Supreme, however, is more expensive than the i-gel - \$25 per device for the LMA Supreme vs \$10.18 per unit for the i-gel. (personnel communication, Major Craig Stachewicz, DHA Medical Logistics, 10 July 2017) It also requires the extra steps of inflating the LMA-Supreme's cuff with air and checking the cuff pressure. Further, when the casualty is transported to definitive care on a helicopter, the pressure in the air-filled cuff on the LMA-Supreme will increase and decrease with altitude changes. The requirement to monitor cuff pressure and add or remove air as needed to maintain the target pressure adds another task that must be performed by busy medics on evacuation platforms. This is a challenge, since these medics may have several critical casualties to care for during the flight. It also means that they will need to train on and carry a cuff manometer.

It is helpful to identify a single device as the EGA of choice in TCCC is that interoperability between combat units would be greatly enhanced if all medics were trained on a single EGA device. Based on the evidence above, the i-gel is the strongest candidate EGA as a standard EGA. The i-gel is presently the only EGA that is used in for ground and helicopter transport of trauma patients in the University of Cincinnati Medical Center's trauma system and the acceptance of the i-gel in that EMS system has been very high, as noted by one of the authors (EJO), who went on to propose that i-gel be selected as the EGA of choice in TCCC. (74)

EGAs in Tactical Field Care as Well as TACEVAC Care

The TCCC Guidelines previously did not recommend the use of extraglottic airways until the TACEVC phase of care. (75) In individuals who are unconscious from hemorrhagic shock or TBI, however, without direct trauma to airway structures, the use of EGAs to manage the casualty's airway offers an opportunity to protect the airway with a device that is easy to insert and that does not entail the small risk of intracranial insertion that NPAs do. Although intracranial insertion of NPAs is rare and has not, to the authors' knowledge, occurred in US casualties from Iraq and Afghanistan, this complication of NPA use has been reported in the literature. (19, 20-23) TCCC training stresses the correct angle of insertion for NPA, which is to avoid the inclination to insert them at the angle that the long axis of the nose forms with the face and to insert them at a more perpendicular angle that tracks along the base of the nasal cavity. This avoids an unwanted cephalad track of the device. (76)

Extraglottic airways are an important, safe, and easy-to-use option that can be added to the combat medic's kit to help manage the airway during Tactical Field Care. Although there is ample evidence to support the use of EGAs in prehospital patients without direct trauma to airway structures, as outlined above, there is less evidence to document the efficacy of EGAs in patients with maxillofacial trauma and airway obstruction. (78) Although one of the authors (EJO) has used the i-gel successfully to secure the airway in two patients with maxillofacial trauma, should the airway become

obstructed as a result of injuries of this type, a surgical airway remains the intervention of choice in TCCC if less invasive measures to open the airway are not successful. (75)

In February of 2017, one of the authors (EJO) presented a recommendation at a CoTCCC meeting that the use of EGA's be extended to the TFC Phase of TCCC. (74)

Confirmation of Correct Placement of EGAs

A 2017 study by Vithalani et al examined 344 attempts at EGA placement (King LTS-D) by prehospital EMS personnel. Successful placement of the EGA was evaluated subjectively by the EMS provider and then confirmed by waveform capnography. While 85% of placements were both subjectively and objectively judged to be successful, 14% of EGA placements that were believed successful by the EMS provider were subsequently found to be misplaced by capnography. The authors emphasize the importance of confirming correct placement of EGAs by EMS personnel through the use of waveform capnography. (78) Pulse oximetry can also help the combat medic, corpsman, or PJ to assess the adequacy of the airway and ventilation.

Summary

The lack of ongoing experience on the part of combat medical personnel at performing ETI and the lack of data for efficacy and improved outcomes for ETI in trauma patients makes this a potentially hazardous airway maneuver in the pre-hospital arena, especially if RSI is not available. (45) The NPA and sit-up and lean-forward positioning will be adequate for some combat casualties, and a surgical airway is the preferred option for casualties with maxillofacial injuries when less invasive airway interventions are not effective.

For combat casualties who are unconscious, but do not have direct airway trauma, there is an increasing role for EGAs. These casualties are unable to protect their airway and may need assisted ventilation as well as supplemental oxygen. EGAs are a good option to maintain a patent airway in such casualties.

The i-gel meets the criteria established by the CoTCCC New Technology Subcommittee and has been shown to perform well in comparison to other EGAs in multiple studies. Further, eliminating the need to fill an EGA cuff with air and then monitor the cuff pressure throughout the evacuation process with a cuff manometer is another very desirable aspect of selecting the i-gel as the EGA of choice; this choice reduces both the equipment and the number of tasks required for the medic to care for his or her casualty.

The i-gel EGA has been shown to be easily trained and there is no good reason not to include its use by ground medics, corpsmen, and PJs in the TFC phase of TCCC in addition to its use by evacuation platform personnel during the TACEVAC phase of care.

Proposed Change to the TCCC Guidelines

Current wording

Tactical Field Care

4. Airway Management

a. Unconscious casualty without airway obstruction:

- Chin lift or jaw thrust maneuver
- Nasopharyngeal airway
- Place casualty in the recovery position

b. Casualty with airway obstruction or impending airway obstruction:

- Chin lift or jaw thrust maneuver
- Nasopharyngeal airway
- Allow a conscious casualty to assume any position that best protects the airway, to include sitting up.
- Place an unconscious casualty in the recovery position.

c. If the previous measures are unsuccessful, perform a surgical cricothyroidotomy using one of the following:

- Cric-Key technique (preferred option)
- Bougie-aided open surgical technique using a flanged and cuffed airway cannula of less than 10 mm outer diameter, 6-7 mm internal diameter, and 5-8 cm of intratracheal length
- Standard open surgical technique using a flanged and cuffed airway cannula of less than 10mm outer diameter, 6-7 mm internal diameter, and 5-8 cm of intra-tracheal length (least desirable option)
- Use lidocaine if the casualty is conscious.

d. Spinal stabilization is not necessary for casualties with penetrating trauma.

Tactical Evacuation Care

3. Airway Management

a. Unconscious casualty without airway obstruction:

- Chin lift or jaw thrust maneuver
- Nasopharyngeal airway
- Place casualty in the recovery position

b. Casualty with airway obstruction or impending airway obstruction:

- Chin lift or jaw thrust maneuver
- Nasopharyngeal airway
- Allow casualty to assume any position that best protects the airway, to include sitting up.
- Place unconscious casualty in the recovery position.

c. If the previous measures are unsuccessful, assess the tactical and clinical situations, the equipment at hand, and the skills and experience of the person providing care, and then select one of the following airway interventions:

- Supraglottic airway, or
- Endotracheal intubation or
- Perform a surgical cricothyroidotomy using one of the following:
 - Cric-Key technique (Preferred option)
 - Bougie-aided open surgical technique using a flanged and cuffed airway cannula of less than 10mm outer diameter, 6-7mm internal diameter, and 5-8 cm of intra-tracheal length
 - Standard open surgical technique using a flanged and cuffed airway cannula of less than 10mm outer diameter, 6-7mm internal diameter and 5-8cm of intra-tracheal length (Least desirable option)
- Use lidocaine if the casualty is conscious.

d. Spinal stabilization is not necessary for casualties with penetrating trauma.

Proposed New Wording

**** New wording in red text***

**** Preserved wording that has been relocated in blue text***

Tactical Field Care

4. Airway Management

a. Conscious casualty with no airway problem identified:

- No airway intervention required

b. Unconscious casualty without airway obstruction:

- Place casualty in the recovery position
- Chin lift or jaw thrust maneuver **or**
- Nasopharyngeal airway **or**
- Extraglottic airway

c. Casualty with airway obstruction or impending airway obstruction:

- Allow a conscious casualty to assume any position that best protects the airway, to include sitting up.
- Use a chin lift or jaw thrust maneuver
- Use suction if available and appropriate
- Nasopharyngeal airway **or**
- Extraglottic airway (if the casualty is unconscious)
- Place an unconscious casualty in the recovery position.

d. If the previous measures are unsuccessful, perform a surgical cricothyroidotomy using one of the following:

- Cric-Key technique (preferred option)
- Bougie-aided open surgical technique using a flanged and cuffed airway cannula of less than 10 mm outer diameter, 6-7 mm internal diameter, and 5-8 cm of intratracheal length
- Standard open surgical technique using a flanged and cuffed airway cannula of less than 10mm outer diameter, 6-7 mm internal diameter, and 5-8 cm of intra-tracheal length (least desirable option)
- Use lidocaine if the casualty is conscious.

e. Cervical spine stabilization is not necessary for casualties who have sustained only penetrating trauma.

f. Monitor the hemoglobin oxygen saturation in casualties to help assess airway patency.

g. Always remember that the casualty's airway status may change over time and requires frequent reassessment.

* The i-gel is the preferred extraglottic airway because its gel-filled cuff makes it simpler to use and avoids the need for cuff inflation and monitoring. If an extraglottic airway with an air-filled cuff is used, the cuff pressure must be monitored to avoid overpressurization, especially during TACEVAC on an aircraft with the accompanying pressure changes.

* Extraglottic airways will not be tolerated by a casualty who is not deeply unconscious. If an unconscious casualty without direct airway trauma needs an airway intervention,

but does not tolerate an extraglottic airway, consider the use of a nasopharyngeal airway.

* For casualties with trauma to the face and mouth, or facial burns with suspected inhalation injury, nasopharyngeal airways and extraglottic airways may not suffice and a surgical cricothyroidotomy may be required.

* Surgical cricothyroidotomies should not be performed on unconscious casualties who have no direct airway trauma unless use of a nasopharyngeal airway and/or an extraglottic airway have been unsuccessful in opening the airway.

Tactical Evacuation Care

3. Airway Management

a. Conscious casualty with no airway problem identified:

- No airway intervention required

b. Unconscious casualty without airway obstruction:

- Place casualty in the recovery position
- Chin lift or jaw thrust maneuver **or**
- Nasopharyngeal airway **or**
- **Extraglottic airway**

c. Casualty with airway obstruction or impending airway obstruction:

- Allow a conscious casualty to assume any position that best protects the airway, to include sitting up.
- Use a chin lift or jaw thrust maneuver
- Use suction if available and appropriate
- Nasopharyngeal airway **or**
- **Extraglottic airway (if the casualty is unconscious)**
- Place an unconscious casualty in the recovery position.

d. If the previous measures are unsuccessful, assess the tactical and clinical situations, the equipment at hand, and the skills and experience of the person providing care, and then select one of the following airway interventions:

- Endotracheal intubation or
- Perform a surgical cricothyroidotomy using one of the following:
 - Cric-Key technique (Preferred option)
 - Bougie-aided open surgical technique using a flanged and cuffed airway cannula of less than 10 mm outer diameter, 6-7 mm internal diameter, and 5-8 cm of intra-tracheal length
 - Standard open surgical technique using a flanged and cuffed airway cannula of less than 10 mm outer diameter, 6-7 mm internal

diameter and 5-8 cm of intra-tracheal length (Least desirable option)

- Use lidocaine if the casualty is conscious.

e. Cervical spine stabilization is not necessary for casualties who have sustained only penetrating trauma.

f. Monitor the hemoglobin oxygen saturation in casualties to help assess airway patency. Use capnography monitoring in this phase of care if available.

g. Always remember that the casualty's airway status may change over time and requires frequent reassessment.

* The i-gel is the preferred extraglottic airway because its gel-filled cuff makes it simpler to use and avoids the need for cuff inflation and monitoring. If an extraglottic airway with an air-filled cuff is used, the cuff pressure must be monitored to avoid overpressurization, especially during TACEVAC on an aircraft with the accompanying pressure changes.

* Extraglottic airways will not be tolerated by a casualty who is not deeply unconscious. If an unconscious casualty without direct airway trauma needs an airway intervention, but does not tolerate an extraglottic airway, consider the use of a nasopharyngeal airway.

* For casualties with trauma to the face and mouth, or facial burns with suspected inhalation injury, nasopharyngeal airways and extraglottic airways may not suffice and a surgical cricothyroidotomy may be required.

* Surgical cricothyroidotomies should not be performed on unconscious casualties who have no direct airway trauma unless use of a nasopharyngeal airway and/or an extraglottic airway have been unsuccessful in opening the airway.

Vote: This proposed change to the TCCC Guidelines was approved by the required 2/3 or more of the Committee on TCCC voting members on 28 August 2017.

Level of evidence:

The levels of evidence used by the American College of Cardiology and the American Heart Association were described by Tricoci in 2009:

- Level A: Evidence from multiple randomized trials or meta-analyses.
- Level B: Evidence from a single randomized trial or nonrandomized

studies.

- Level C: Expert opinion, case studies, or standards of care. **(79)**

Using this taxonomy for evidence, the Levels of Evidence that support the following statements is shown below:

1. Extraglottic airways can be safely and effectively used by prehospital personnel to maintain a patent airway in patients without direct trauma to airway structures.

Level B

2. The i-gel is the EGA of choice for combat medical personnel in TCCC.

Level C

Considerations for Further Research and Development

1. For how many casualties in Iraq and Afghanistan would extraglottic airways been appropriate for use?

2. How many casualties in Iraq and Afghanistan had surgical airways performed when they had no maxillofacial trauma or trauma to other airway structures?

3. The data in the DoD Trauma Registry should be searched periodically for prehospital care reports of EGA use (both i-gel and other) with attention to; the number of uses; indications for use; whether or not other airway interventions were also attempted; reported complications; and the success rates for the various types of EGAs.

4. The data in the DoD Trauma Registry should be searched periodically for prehospital care reports of NPA use with attention to: the number of uses; indications for use; whether or not other airway interventions were also attempted; reported complications; and the success rates for the various types of EGAs.

5. The data in the DoD Trauma Registry should be searched for prehospital care reports to determine how many surgical airway attempts might have been avoided through use of an EGA or an NPA.

6. Ongoing preventable death analysis in US combat fatalities should be performed to determine which fatalities were due to unrelieved airway obstruction and which airway interventions were attempted for these fatalities.

7. Ongoing preventable death analysis in US combat fatalities should be performed to determine whether or not there any deaths identified in which the casualties were unconscious and lost their airway, but did not have direct trauma to airway structures.

8. Ongoing preventable death analysis in US combat fatalities should be performed to determine whether or not there any deaths identified as a result of patients with a decreased state of consciousness having an NPA or extraglottic airway used instead of having a surgical airway performed. (As might occur with an episode of vomiting with aspiration and subsequent respiratory failure.)
9. The DoD should fund prospective comparative studies of EGA use in trauma patients, both with and without maxillofacial injuries, comparing the i-gel to other EGA options.
10. The DoD should fund prospective studies of i-gel use in comparison to NPA use in trauma patients, both with and without maxillofacial injuries, and with and without blunt head trauma.
11. Attention should be directed during JTS trauma teleconferences to identifying casualties in whom attempted placement of an EGA or an NPA resulted in vomiting and/or aspiration during the insertion attempt or subsequently.
12. Field intubation **(80)** and hypoxia **(81)** have been associated with worsened outcomes in TBI patients. Studies should be performed to observe the effect of airway management with NPAs and EGAs in TBI patients.

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Disclaimers

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense. This recommendation is intended to be a guideline only and is not a substitute for clinical judgment.

Disclosures

The authors have no disclosures.

Release

This document was reviewed by the Director of the Joint Trauma System and by the Public Affairs Office and the Operational Security Office at the U.S. Army Institute of Surgical Research. It is approved for unlimited public release.

Author Biographies

CAPT (Ret) Edward J. (Mel) Otten is a former Army sergeant who served as a combat medic during the Vietnam conflict. He also served with the Marine Corps and retired from the Navy with the rank of Captain. He has more than 35 years of Special Operations experience. Currently, he is a Distinguished Professor of Emergency Medicine and Pediatrics and Director, Division of Toxicology, at the University of Cincinnati Medical Center, Cincinnati, Ohio.

MSG (Ret) Harold (Monty) Montgomery, USA, is a retired Ranger Medic/Special Operations Combat Medic, having served as the Senior Enlisted Medical Advisor at USSOCOM and as the Regimental Senior Medic of the 75th Ranger Regiment for a combined 25 years with multiple combat deployments. He is currently the Operational Medicine Liaison for the Joint Trauma System and the Committee on Tactical Combat Casualty Care.

CAPT (Ret) Frank Butler, USN, was a Navy SEAL platoon commander before becoming a physician. He is an ophthalmologist and a Navy Undersea Medical Officer with over 20 years of experience providing medical support to Special Operations Forces. Dr. Butler served as the Command Surgeon for the US Special Operations Command and is currently the Chairman of the Committee on TCCC and Chief of Prehospital Trauma Care at the Joint Trauma System.