

Proposal for the Use of i-Gel Airways for Certified NYS Emergency Medical Technicians During the Treatment of Adults in Cardiac Arrest

A pilot project presented by the
Greenville Township Volunteer Ambulance Corps and the
Hudson Valley Regional EMS Council

Update: JULY 8, 2022



Introduction

The Greenville Township Volunteer Ambulance Corps brought the idea of using i-gel Supraglottic Airways by NYS Certified Emergency Medical Technicians (EMT) to the Hudson Valley Regional Medical Advisory Committee (HVREMAC) as a pilot project of the Regional Council in February 2020. After consideration and discussion, the HVREMAC brought forth the idea to the New York State Medical Advisory Committee (SEMAC) who approved the draft with revisions to be approved by New York State EMS Council (SEMSCO) for approval by the New York State Commissioner of Health in 2021. This document reflects the proposed pilot project with revisions by the HVREMAC, SEMAC, SEMSCO, and Commissioner of Health as of April 2022.

Proposal

This pilot project will study the feasibility of Emergency Medical Technicians to successfully utilize an i-gel type gel supraglottic airway device during the treatment of adult patients in cardiac arrest.

Requirements

Emergency Medical Technicians engaged in this pilot must be currently certified by the NYS DOH BEMS, have completed the most current protocol update, and are members in good standing of the agency engaged in this project.

EMTs may only utilize this procedure through a NYS Certified Agency that is Regionally approved for this study. EMTs working for or volunteering with another agency NOT engaged in this project CAN NOT utilize this procedure when providing patient care through such agency.

Agencies engaged in this project MUST be New York State Certified and in good standing with the NYS DOH BEMS.

Participating agencies must have written support and approval by their Medical Director.

Local Regional EMS Councils must approve the participation of agencies in their respective regions, and forward agency applications and written approvals to the Hudson Valley Regional EMS Council for final approval.

Participating agencies must utilize a NYS approved ePCR system and provide usage data that meets NEMSIS 3.4 standards.

Participating agencies, and providers engaged in the i-gel pilot, must currently be using all approved BLS Adjuncts.

All EMTs using this method of airway management must participate in a didactic and psychomotor training program and successfully complete cognitive and psychomotor skills testing administered by NYS Certified Instructor Coordinators (CIC), Certified Lab Instructors (CLI) and/or medical director approved training officers.

EMTs must use an i-gel supraglottic airway resus-pack device.

EMTs must use waveform capnography with each gel supraglottic airway placement.

EMTs must request Advanced Life Support (ALS) with each i-gel supraglottic airway use.

Each i-gel supraglottic airway placement must be confirmed by either an ALS provider or an emergency department medical control Nurse Practitioner (NP), Physician Assistant (PA) or Physician (MD/DO).

EMTs must document all aspects of use, placement confirmation, and verification names and signatures in their ePCR and report any adverse patient outcomes.

Agencies must engage in quality assurance of all uses and reposit data to the HVREMSCO.

Term

This pilot project will run for two years unless sufficient data supports the termination of the pilot earlier.

Justification

Providing airway control during cardiac arrest at the BLS level is limited to the use of oropharyngeal and nasopharyngeal airways, suctioning, and airway maneuvers such as head extension and jaw thrust. Additionally, one of the most difficult skills is maintaining a good mask seal when performing bag-valve-mask ventilations especially with limited personnel.

With a decreasing EMS workforce, it is important for providers, agencies, and systems to utilize all available methods of efficiency since resources are increasingly spread out or unavailable. One of the greatest efficiencies is in utilizing BLS providers who can treat patients by using all the available BLS adjuncts approved by the NYS DOH BEMS. Paramedic resources are spread thin across the state and ALS units are often arriving on the scenes well after BLS crews, if at all.

Another step forward would be allowing trained and equipped EMTs to utilize a gel supraglottic airway. EMTs using such an airway has many benefits and is well represented in an increasing number of current studies. Some benefits include that they are placed blindly, require less training time, can be placed in less time, and are easier to place during chest compressions (Sullivan, 2018), and the only barrier to using such a device is the local scope of practice (DeBoer, 2015).

An EMT placing a gel supraglottic airway leads to increased time and skill management on the scene of patients suffering a cardiac arrest. EMTs can control an airway in the first few minutes of arrival and allow ALS providers to focus their attention on other aspects of patient care including the overall treatment of the patient and not just one skill at a time.

Another critical aspect of EMTs using a gel supraglottic airway is the value of airway management while not interrupting chest compressions. Current resuscitation guidelines emphasize that interrupting chest compressions should be limited to few circumstances. EMTs using a gel supraglottic airway meet two criteria in such guidelines: ensuring a good airway in a short amount of time and placing such an airway without interrupting chest compressions. Intersurgical, the manufacturer of the i-gel supraglottic airway indicates that a provider experienced with the device can place it in five (5) seconds and that compressions do not need to be stopped for placement (Intersurgical, 2022).

A complement to early airway management while not interrupting chest compressions is that current generation supraglottic airways help to relieve gastric insufflation by way of gastric decompression ports and higher oropharyngeal leak pressures (Intersurgical, 2022) which makes them better devices for emergency airway management (Dodd, Strobel, Driver, Reardon, 2016). Since significant gastric insufflation can impede adequate ventilation and oxygenation, EMTs utilizing an i-gel can direct ventilation to the trachea and also relieve gastric insufflation through the gastric decompression port while not stopping or delaying CPR, thereby improving patient care and potential outcomes.

A follow up study from 2017 in a large ground and air-based EMS agency found that “deployment of the i-gel substantially improved overall invasive airway success” (Lyng, Perlmutter, Trembley, Conterato & West, 2017).

To sum this section, a National Association of Emergency Medical Services Physicians (NAEMSP) position paper indicates that “manual ventilation using a self-inflating bag device paired with a facemask is a fundamental airway management skill for all Emergency Medical Services (EMS) clinicians” but that “delivery of manual ventilations is challenging” (Lyng, Guyette, Levy, & Bosson, 2022). The authors attribute difficulties in Bag Valve Mask (BVM) ventilation to inadequate mask seal, excessive resistance to entry or exit of air, high body mass index, lack of teeth, presence of a beard, history of snoring, limited availability of personnel, providing care in sub-optimal settings, and rescuer/patient positioning challenges (Lyng, Guyette, Levy, & Bosson, 2022). While increased training and practice would help providers overcome some of the situations above, the use of a gel supraglottic airway would help to alleviate many others. The i-gel, coupled with waveform capnography, would help EMTs to create a better airway.

Risks of Using the i-gel

While the anatomical design and material of the i-gel are less likely to cause adverse outcomes when compared to other supraglottic devices (Intersurgical, 2022), there are risks. These include the device being inserted to the correct depth for the ventilation port to be over the glottic opening, inadequate ventilation, inadequate protection from aspiration, and an inability to detect lung sounds after placement (Sullivan 2018). Additionally, supraglottic devices are ineffective for patients with upper airway edema, such as from burns or anaphylaxis, and with patients with masses or tumors (Intersurgical, 2022). Such conditions are contraindications to use.

Other known risks and complications of the use of supraglottic airway devices include laryngospasm, sore throat, trauma to the pharyngo-laryngeal framework, gastric insufflation, regurgitation and inhalation of the gastric contents, nerve injuries, vocal cord paralysis, lingual or hypoglossal nerve injuries, tongue numbness and cyanosis (Intersurgical, 2022).

Placement issues include the risk of rotation and mispositioning, leading to partial or complete airway obstruction, but which is extremely low with the i-gel as compared with other supraglottic devices. Also, down-folding of the epiglottis can occasionally occur and may be more common in children, but the i-gel’s cuff and airway channel reduce the chances of obstruction (Intersurgical, 2022).

If an EMT places the i-gel too high in the pharynx, this may result in a poor seal and cause excessive leakage. Much like a BVM, should a provider apply excessive force while ventilating, by squeezing the reservoir bag too quickly, this may cause gastric insufflation and distension, which will increase the risk of regurgitation (Intersurgical, 2022).

If the tip of the i-gel enters into the glottic opening, this can lead to an excessive air leak through the gastric channel, which may result in obstruction and if a Naso-Gastric Tube (NGT) is then inserted through the gastric port, it will enter into the trachea and lungs (Intersurgical, 2022).

Mitigating the above risks occurs through diligent and comprehensive education and training, on-going reassessment of skills, use of waveform capnography, continual re-assessment of the i-gel once placed, confirmation of placement by trained providers at higher levels of care, and quality-assurance oversight.

Gel Supraglottic Airway Insertion for EMTs

Criteria

For adult patients who are unresponsive without signs of life

Contraindications

Patients with a stoma
Obstructive lesions below the glottis
Trismus or limited mouth opening
Pharyngo-perilaryngeal abscess, trauma or mass
Caustic ingestion

CFR

- Follow Adult Cardiac Arrest protocol
- Call for ALS



CFR STOP

EMT

1. Follow Adult Respiratory Arrest / Failure protocol components:
 - Open the airway using the head-tilt/chin-lift or modified jaw-thrust maneuver
 - Remove any visible airway obstruction by hand
 - Clear the airway of any accumulated secretions or fluids by suctioning
 - Provide positive pressure ventilation using a bag-valve mask
 - If ventilations are not successful, refer immediately to the “Extremis: Foreign Body Obstructed Airway” protocol
 - BLS airway management with use of airway adjuncts and bag-valve mask device, as indicated, including suction as needed, if available
 - Bag-valve mask should be connected to supplemental oxygen, if available
 - Ventilate every 5-6 seconds (adult patient)
 - Each breath is given over 1 second and should cause visible chest rise
2. Prepare and insert Gel Supraglottic Airway as per manufacturer's instructions
3. Attach and monitor waveform capnography
4. Confirm presence of bilateral lung sounds
5. Confirm absence of epigastric sounds
6. Secure the Gel Supraglottic Airway as per manufacturer's instructions
7. Continue to ventilate the patient as you would if no supraglottic airway was in place
8. If ALS intercepts, an ALS provider must confirm correct placement
9. If no ALS is available, the emergency department Medical Control NP, PA, or Physician (MD/DO) must confirm placement
10. Document in the ePCR all confirmation methods used to confirm correct placement

MEDICAL CONTROL CONSIDERATIONS

- Insert Gel Supraglottic Airway if approved, trained, and equipped

Key Points/Considerations

- Do not delay beginning compressions to begin ventilations
- Do not delay ventilations to connect supplemental oxygen
- Adequate ventilation may require disabling the pop-off valve if the bag-valve mask unit is so equipped
- Do not interrupt compressions for placement of an airway
- Ongoing assessment is required to assess the effectiveness of ventilations
- Do not delay transport

Evaluation of Use

Local agencies must perform quality assurance evaluations on each i-gel supraglottic airway use by EMTs in the pilot program within 24-48 hours of use and notify the HVREMSCO within 72 hours of use.

Quality assurance must minimally include:

- appropriateness of use
- adherence to protocol
- time to use, placement, confirmation
- use of waveform capnography
- any side-effects, issues, complications or equipment failure
- placement confirmation sign-off
- comprehensiveness of documentation
- patient outcome

All training, evaluation, and quality assurance documents must be maintained at the agency for at least seven (7) years and must be made available upon request by representatives of the NYS DOH Bureau of EMS.

The HVREMSCO will develop and make available an online survey for provider use to provide feedback about training, use, complications, and any suggestions.

The HVREMSCO will collect HIPAA compliant data on i-gel supraglottic airway use by approved EMTs throughout the State through the Imagetrend Elite State Bridge. The HVREMSCO will maintain data in a shareable format and review all cases upon receipt. The HVREMSCO will forward results to the HVREMAC Chair on a weekly basis. The HVREMAC Chair or their designee will provide quarterly updates to participants and interested SEMSCO Committees. At the conclusion of the study, the HVREMSCO will compile all data and provide a report to participants, SEMAC, SEMSCO, and the Commissioner of Health. The HVREMAC Chair, SEMAC, SEMSCO, or Commissioner of Health may stop the study for evaluation at any point due to compelling data for success or otherwise.

The HVREMSCO will minimally evaluate the following data points based on an initial criterion of i-gel use:

- Patient Age
- Patient Gender
- Patient Weight (kg)
- Bystander AED
- Bystander CPR
- EMS AED
- LUCAS CPR or equivalent device
- Suction
- Oral / Nasal Airway
- Bag Valve Mask
- Oxygen
- Verification methods
- Waveform Capnography
- Number of attempts
- I-gel size
- Return of Spontaneous Circulation
- ALS intercept
- ALS confirmation of placement
- I-gel removal
- Medical Control confirmation of placement
- Call / treatment times

Participating agencies must meet all requirements and agree to all terms and conditions contained in this pilot project. Interested agencies must apply to the HVREMSCO through their local REMSCO. Upon receipt of application, the HVREMSCO will contact the agency, review the pilot and requirements, and provide all training materials.



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Application for Participation in the i-gel Supraglottic Airway Pilot Program

Agency Name: _____ Agency Code: _____

Agency Address: _____

Agency Phone #: _____ Go-Live Date: _____

Agency Contact Name: _____ Phone Number: _____

Agency Contact Email: _____

e-PCR Vendor: _____

Agency Medical Director: _____ Phone Number: _____

Medical Director Email: _____

Medical Director Affiliated Hospital: _____

Agency Region: _____ Date of Application: _____

Region Contact Name: _____ Phone Number: _____

Region Contact Email: _____

Signature of Agency Official _____ Date _____

Signature of Medical Director _____ Date _____

Signature of Regional Representative _____ Date _____

Upon submission of this application, agencies participating in the HVREMSCO i-gel Supraglottic Airway Pilot Program agree to all administrative, training, testing, quality assurance, reporting, and record-keeping requirements of the program as listed in the Pilot Project Proposal.

i-gel Psychomotor Competency

Candidate: _____

Agency: _____

Procedure	Successful	Unsuccessful
Takes appropriate PPE precautions		
Preoxygenates the patient appropriately		
Opens the i-gel package and removes the i-gel from the cradle		
Applies lubricant to the cradle		
Applies lubricant to the sides, back, and tip of the i-gel cuff		
Ensures that there is no lubricant in the bowl		
Replaces the i-gel in the cradle until ready to insert		
Removes the i-gel from the cradle and grasps it by the integral bite block		
Inserts the i-gel into the oropharynx with gentle constant pressure		
Stops insertion when definitive stop is felt		
Notes the placement of the i-gel at the teeth		
Applies waveform capnography and notes appropriate reading		
Listens to sounds over the epigastrium		
Listens to sounds in bilateral apexes		
Listens to sounds in bilateral bases		
Listens to sounds in bilateral midaxillaries		
Secures the device		
Ensures proper ventilatory rate and depth		
Recognizes need to remove the device		
Verbalizes continued care		
Verbalizes need to document procedure in PCR		

Critical Criteria

- _____ Failure to take or verbalize appropriate PPE precautions
- _____ Undue amount of force used to insert the i-gel
- _____ Candidate hyperventilated the patient pre/post i-gel insertion
- _____ Failure to check lung / epigastric sounds or to attach waveform capnography
- _____ Failure to secure the device properly

Evaluator Name _____ Credentials _____

Evaluator Signature _____ Date _____

Candidate Signature _____

References

- DeBoer, S. (2015). *Alternative Airways: The Who, What, Where, When and How*. Hmpgloballearningnetwork.com. Retrieved April 6, 2022, from <https://www.hmpgloballearningnetwork.com/site/emsworld/article/12107883/alternative-airways>
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- Intersurgical. (2022). Gel® Supraglottic Airway. Retrieved April 6, 2022, from <https://www.intersurgical.com/products/airway-management/i-gel-supraglottic-airway>
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- Lyng, J., Perlmutter, M., Trembley, A., Conterato, M., & West, M. (2017). 37 Supraglottic Airway Use vs Endotracheal Intubation Pre/Post Deployment of the i-gel Supraglottic Airway Device in a Large Ground and Air-based Emergency Medical Services Agency. *Annals of Emergency Medicine*, 70 (4) S15.
- Sullivan, B. (2018). *3 things EMS providers need to know about supraglottic airways*. EMS1. Retrieved April 6, 2022, from <https://www.ems1.com/ems-products/medical-equipment/airway-management/articles/3-things-ems-providers-need-to-know-about-supraglottic-airways-UfFKKttSkvl2Fjdf/>