# Ventilation and Airway Optimization for Cardiac Arrest Resuscitation (VENTOR) Study

Jignesh Patel, MD

# Objectives

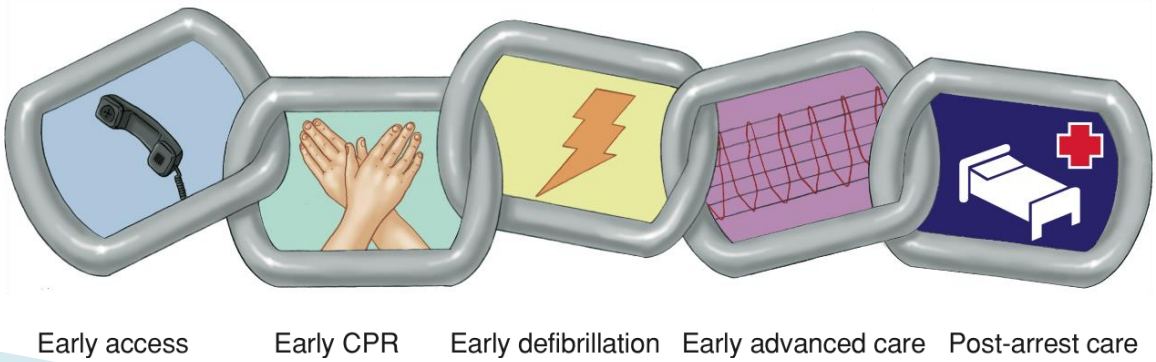
- Discuss what is cardiac arrest?
- Discuss the current treatment for cardiac arrest.
- Explain the Ventor Airway System.
- Explain the VENTOR study and what it is trying to accomplish.
- Discuss emergency research and consent.

# About Cardiac Arrest

- Cardiac arrest (AKA sudden cardiac arrest or cardiopulmonary arrest) is the sudden loss of cardiac function, when the heart abruptly stops.
- Cardiac arrest stops blood circulation and prevents delivery of oxygen and glucose to the body.
- Lack of oxygen and glucose for more than five minutes causes brain injury.
- For the best chance of survival and neurological recovery, immediate and decisive treatment is imperative.
- Despite adequate CPR, the survival rate from cardiac arrest remains very low.

# Cardiac Arrest

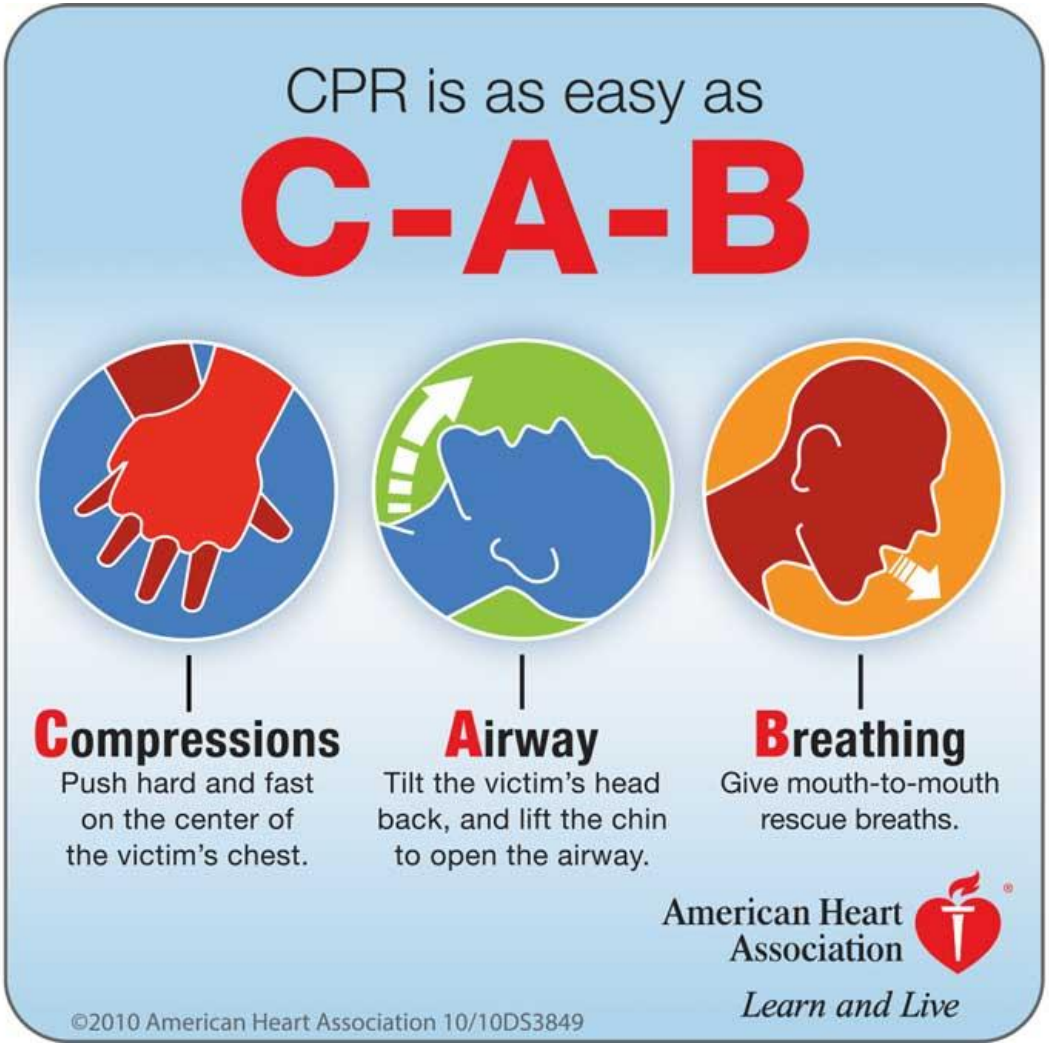
- A minority of patients survive in-hospital cardiac arrest even with a rapid sequence of events.
  - Chain of survival:
    - Early recognition and CODE team
    - Immediate CPR
    - Early defibrillation
    - Early advanced cardiac life support
    - Integrated post-arrest care



# Importance of CPR

- Why is CPR Important?
  - Studies show that circulating oxygenated blood with CPR increases the odds of survival
  - Chest compressions can be started within 18 seconds of arriving at the patient, whereas providing airway management first can delay compressions by 1-2 minutes or more
  - CPR prolongs the period during which defibrillation and other definitive care can be effective

# The Current Priorities During CPR

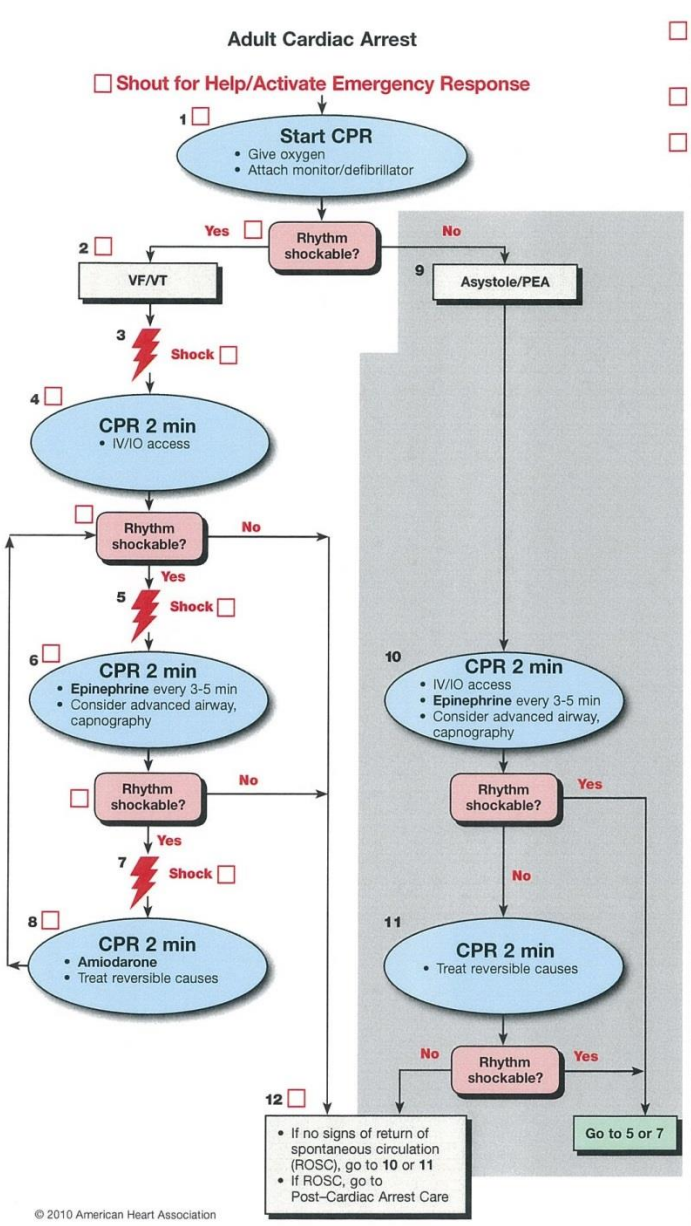



- 2020 AHA Guidelines

# ACLS Guidelines

- Adult Cardiac Arrest

# Cardiac Arrest VF/Pulseless VT Learning Station Checklist




**CPR Quality**
- Push hard (≥2 inches [5 cm]) and fast (≥100/min) and allow complete chest recoil
- Minimize interruptions in compressions
- Avoid excessive ventilation
- Rotate compressor every 2 minutes
- If no advanced airway, 30:2 compression-ventilation ratio
- Quantitative waveform capnography
  - If $P_{ETCO_2}$ <10 mm Hg, attempt to improve CPR quality
- Intra-arterial pressure
  - If relaxation phase (diastolic) pressure <20 mm Hg, attempt to improve CPR quality

**Return of Spontaneous Circulation (ROSC)**
- Pulse and blood pressure
- Abrupt sustained increase in $P_{ETCO_2}$ (typically ≥40 mm Hg)
- Spontaneous arterial pressure waves with intra-arterial monitoring

**Shock Energy**
- **Biphasic:** Manufacturer recommendation (eg, initial dose of 120-200 J); if unknown, use maximum available. Second and subsequent doses should be equivalent, and higher doses may be considered.
- **Monophasic:** 360 J

**Drug Therapy**
- **Epinephrine IV/IO Dose:** 1 mg every 3-5 minutes
- **Vasopressin IV/IO Dose:** 40 units can replace first or second dose of epinephrine
- **Amiodarone IV/IO Dose:** First dose: 300 mg bolus. Second dose: 150 mg.

**Advanced Airway**
- Supraglottic advanced airway or endotracheal intubation
- Waveform capnography to confirm and monitor ET tube placement
- 8-10 breaths per minute with continuous chest compressions

**Reversible Causes**
- **H**ypovolemia
- **H**ypoxia
- **H**ydrogen ion (acidosis)
- **H**ypo-/hyperkalemia
- **H**ypothermia
- **T**ension pneumothorax
- **T**amponade, cardiac
- **T**oxins
- **T**hrombosis, pulmonary
- **T**hrombosis, coronary

# Reasoning for de-emphasizing airway and ventilation during cardiac arrest

- Establishing an advanced airway, also known as endotracheal intubation, interrupts other vital care such as chest compressions.
- Pushing air into the lungs, also known as positive pressure ventilations, may reduce critical blood flow during CPR.

# Research has also shown ventilation is important during CPR

- Increased oxygen in the blood during CPR has shown to have a significant effect on cardiac arrest survival.
- Patients that were ventilated well during the first 8 minutes of CPR had higher changes of surviving cardiac arrest.

# The Purpose of the VENTOR study

To initially evaluate the safety and effectiveness of the Ventor Airway System, which aims to reduce interruptions to vital care during insertion and increase the circulation of oxygen during CPR with a ventilation technique more conducive to chest compressions.

# Proposed Intervention

- The Ventor Airway System will be used on adult patients experiencing cardiac arrest in the hospital.
- The patient will receive all other standard of care during cardiac arrest and after.
- Several measurements (such as blood samples) will be taken during and after the device use to initially evaluate its safety and effectiveness.

# Procedure Description

- The Ventor Airway is a tube that will be inserted through the patient's mouth that is designed to deliver oxygen to the lungs.
- It is connected to a small console (instrument) that is designed to deliver the oxygen through the tube in a safe and efficient way.
- The Ventor System is designed to not distract the CPR care provider from giving chest compressions.
- The Ventor Airway System is only meant to be used during CPR and shortly after.

# Who will participate in the study?

- Adult subjects who are taller than 4 feet who:
  - do not already have an airway in place
  - did not object to CPR or participating in the study before the cardiac arrest event
  - do not have conditions or diseases that could possibly prevent the device from working safely in them

# Risk Associated with the VENTOR Study

- Device-Specific Risks
- Operational Risks
- Study-Related Risks

# Device-Specific Risks

- **Airway Misplacement**: The device might be incorrectly placed in the throat or esophagus.
- **Negative Pressure**: Potential injury to the esophagus due to the device's negative pressure feature.
- **Device Malfunction**: Mechanical issues, such as incorrect ventilation rates or power failure.
- **Unknown Risk:** With any new device there are always unknown risks.

# Operational Risks

- Difficulties in inserting the device, leading to delays in treatment.
- Improper ventilation causing either too much or too little air to the lungs.
- Risk of aspiration (inhaling stomach contents into the lungs), which can lead to infections.

# Study-Related Risks

- Additional procedures required for the study, such as blood gas sampling and esophagoscopy, carry their own risks.
- Conducting the study under emergency conditions might mean not getting informed consent in the usual way.
- Breach of patient confidentiality.

# Potential Benefits Associated with the VENTOR Study

- Improved Oxygenation and Ventilation
- Ease of Use
- Reduction in Complications

# Improved Oxygenation and Ventilations

- The device is designed to enhance oxygen delivery during CPR, which is critical for brain and organ function.
- Potentially higher survival rates and better neurological outcomes due to more effective oxygenation.

# Ease of Use

- Simplifies the process of securing an airway, making it quicker and easier for medical personnel, even in high-stress situations.
- Reduces the chance of errors compared to traditional methods, which can be more complex and time-consuming.

# Reduction in Complications

- Provides automated ventilations, synchronized with chest compressions, ensuring more consistent and effective delivery of breaths.
- Reduces the risk of over- or under-ventilation, which can be harmful.
- Designed to minimize the risk of air entering the stomach, which can cause complications like vomiting and aspiration.

# Difference between research and treatment

| Clinical Research Versus Medical Treatment | | |
|---|---|---|
| | **Clinical Research** | **Medical Treatment** |
| **Intent** | Answers specific questions through research involving numerous research volunteers. | Address the needs of individual patients. |
| **Intended Benefit** | Generally designed and intended to benefit future patients. | Intended to benefit the individual patient. |
| **Funding** | Paid for by drug developers and government agencies. | Funded by individual patients and their health plans. |
| **Timeframe** | Depends on the research protocol. | Requires real-time decisions. |
| **Consent** | Requires written informed consent. | May or may not require informed consent. |
| **Assessment** | Involves periodic and systematic assessment of patient data. | Based on as-needed patient assessment. |
| **Protections** | Protected by government agencies, institutional review boards, professional standards, informed consent, and legal standards. | Guided by state boards of medical practice, professional standards, peer review, informed consent, and legal standards. |
| **Certainty** | Tests products and procedures of unproven benefit to the patient. | Uses products and procedures accepted by the medical community as safe and effective. |
| **Access to Information** | Considered confidential intellectual property. | Available to the general public through product labeling. |
| **Release of Findings** | Published in medical journals, after clinical research ends. | Individual medical records are not released to the general public. |

# How are emergency studies different from other studies?

- In most studies, investigators describe what will happen, discuss potential risks and benefits, answer questions, and then eligible patients decide whether or not to participate. This process is called informed consent.
- In this study, eligible patients are unresponsive and cannot communicate or decide if they want to participate in the study. Also, treatment will likely need to be started before a family member or legal representative is available to provide consent for the patient.

# How are emergency studies conducted?

- Special Federal regulations allow for exception from informed consent (EFIC) for emergency research.
- EFIC is only allowed when: the condition is life-threatening, existing treatments are unproven or inadequate, there is potential benefit from the research, and informed consent cannot be obtained.

# What if I don't want to be in VENTOR?

- Ask for an Opt-Out Card, bracelet, or necklace that indicates you do not want to participate.
- Call your local study team to have your preferred opt-out method sent to you.
- Visit the VENTOR website to print an Opt-Out Card.
- If you have a cardiac arrest, you will not be enrolled if you are carrying the Opt-Out Card, bracelet, or necklace.

# What do you think about VENTOR?

- The study hasn't started yet, so we want to hear your thoughts.
- Tell us about your experiences.
- Do you think it is OK for the study to be done?
- The study team and medical review board will consider your input in deciding whether it is OK for this study to be done in our community.

# Questions

- If you have any concerns or questions, please call us or contact us.
- Principal Investigator: [Name, phone number, email]
- Study Coordinator: [Name, phone number, email]