

# Comparison of adult self-inflating bag versus pediatric self-inflating bag in adult cardiac arrest patients who have been intubated

<b>Submission date</b> 12/12/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/12/2024	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Avoiding excessive ventilation is one of the key components of high-quality cardiopulmonary resuscitation (CPR). European Resuscitation Council (ERC) 2021 guidelines recommend each breath over 1 second just enough to achieve a visible chest rise during CPR to avoid excessive ventilation. American Heart Association (AHA) 2020 guidelines recommend enough tidal volume to cause visible chest rise, or approximately 500 to 600 mL, while minimizing the risk of overdistension or gastric inflation. Adult self-inflating bags are used widely to ventilate cardiac arrest patients. Total volume of the standard adult self-inflating bag is 1600ml. Tidal volume during manual ventilation varies greatly depending on the practitioner thus delivering approximately 600-1000ml. This in turn will lead to excessive ventilation which is harmful during CPR. Thus, this study intends to use pediatric self-inflating bags (750ml). With the usual squeeze of half to 2/3rd of total capacity, the tidal volume delivered is anticipated to be approximately 400-550ml, which would be guideline-consistent for adequate ventilation during CPR. This study will enlighten us regarding the average tidal volume being delivered by adult and pediatric self-inflating bags during CPR.

### Who can participate?

Adult patients (above 18 years old) experiencing cardiac arrest

### What does the study involve?

The study will commence after obtaining approval from the Institute Ethics Committee. Adult patients (above 18 years) experiencing cardiac arrest will be treated according to standard guidelines in the emergency department. All eligible patients will be included in the study.

During standard CPR, a flow analyzer will be connected between the endotracheal tube and the adult self-inflating bag. This device records ventilatory metrics such as inspired and expired tidal volume, peak flow, inspiratory time, and breaths per minute over 2 minutes, with the display monitor covered.

For patients achieving a return of spontaneous circulation (ROSC), post-cardiac arrest care will be provided. For those failing to achieve ROSC and meeting termination-of-resuscitation criteria, and when resuscitation is deemed futile by the treating physicians, CPR will be extended for 2 minutes using a pediatric self-inflating bag. Ventilatory metrics will be recorded for the pediatric bag, and the tidal volume required for visible chest rise will be considered the ideal tidal volume for that patient.

This study aims to compare the ideal tidal volume with the average tidal volumes delivered by adult and pediatric self-inflating bags.

What are the possible benefits and risks of participating?

As the study is performed on a cardiac arrest patient who reaches the termination of the resuscitation criteria - the patient would neither benefit nor be harmed. There is no anticipated risk except the waiver of consent.

Where is the study run from?

Jawaharlal Institute of Postgraduate Medical Education and Research (India)

When is the study starting and how long is it expected to run for?

August 2022 to January 2024

Who is funding the study?

Jawaharlal Institute of Postgraduate Medical Education and Research (India)

Who is the main contact?

Dr Kowsthubha B G, beingmedico149@gmail.com, jr7374@jipmer.ac.in (India)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Kowsthubha B G

### ORCID ID

<https://orcid.org/0009-0006-7909-7248>

### Contact details

Emergency Medicine and Trauma  
EMS Block, JIPMER  
JIPMER Campus Road, Danavanthari Nagar  
Puducherry  
India  
605006  
+919008801986  
jr7374@jipmer.ac.in

### Type(s)

Public, Scientific

**Contact name**

Dr Manu Ayyan S

**ORCID ID**

<https://orcid.org/0000-0002-2541-5769>

**Contact details**

Associate professor  
Emergency medicine and trauma  
EMS Block, JIPMER  
JIPMER Campus Road, Danavanthari Nagar  
Puducherry  
India  
605006  
+919846556133  
manuayyan.s.jir@nic.in

**Type(s)**

Public, Scientific

**Contact name**

Dr Anandhi Devendiran

**ORCID ID**

<https://orcid.org/0000-0003-3498-6392>

**Contact details**

Puducherry  
Puducherry  
India  
605006  
+919626064984  
anandhideva1@gmail.com

**Type(s)**

Public

**Contact name**

Dr Kowsthubha B G

**Contact details**

Emergency Medicine and Trauma  
EMS Block, JIPMER  
JIPMER Campus Road, Danavanthari Nagar  
Puducherry  
India  
605006  
+919008801986  
beingmedico149@gmail.com

**Type(s)**

Public

**Contact name**

Dr Manu Ayyan S

**Contact details**

Associate professor  
Emergency medicine and trauma  
EMS Block, JIPMER  
JIPMER campus road, danavanthari nagar  
Puducherry  
India  
605006  
+919846556133  
manuayyan@hotmail.com

**Additional identifiers**

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

Nil known

**Study information**

**Scientific Title**

Extended cardiopulmonary resuscitation using a pediatric self-inflating bag in adult cardiac arrest patients reaching termination-of-resuscitation criteria – a prospective interventional study

**Study objectives**

Expected outcome and application

The tidal volumes provided by standard adult self-inflating bags may be causing harm in practical use.

1. This study will enlighten us regarding the average tidal volume being delivered by an adult self-inflating bag during CPR.
2. Pediatric self-inflating bags are expected to deliver appropriate tidal volume to ventilate intubated adult cardiac arrest patients.
3. The ideal tidal volume required to achieve a visible chest rise in adult cardiac arrest patients will be known which will help us to determine if a pediatric or adult self-inflating bag delivers guideline-consistent ventilation.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 06/08/2022, Institutional Ethics Committee (Human studies) for Intervention studies (Jawaharlal Institute of Postgraduate Medical Education and Research JIPMER Campus Rd, Gorimedu, Dhanvantari Nagar, Puducherry, 605006, India; +91 0413-2277278; research@jipmer.edu.in), ref: JIP/IEC/2022/034

## **Study design**

Clinical prospective non-randomized interventional study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Airway management during adult extended CPR using an adult inflating bag versus a pediatric self-inflating bag

## **Interventions**

The study will be started after obtaining the Institute Ethics Committee's Approval.

Adult patients (>18 years) in cardiac arrest will be resuscitated as per standard recommended guidelines in the emergency department.

All eligible patients will be enrolled in the study.

When conventional CPR is in progress, a flow analyser (with the display monitor covered by an opaque plaster) will be connected between the endotracheal tube and the adult self-inflating bag (1600 ml).

Ventilatory metrics (inspired and expired tidal volume, peak flow, inspiratory time, breaths per minute) delivered by an adult self-inflating bag with ongoing chest compressions will be recorded over 2 minutes and average measurements will be noted.

1. Patients who achieve a return of spontaneous circulation (ROSC) will receive post-cardiac arrest as per care
2. For Patients who fail to achieve ROSC, reach termination-of-resuscitation criteria and in whom, continued resuscitation is declared futile by the treating team of physicians (who are not part of the study), CPR will be extended for 2 minutes using a pediatric self-inflating bag (750 ml) to ventilate.

Ventilatory metrics (inspired & expired tidal volume, peak flow, inspiratory time, breaths per minute) delivered by the pediatric self-inflating bag with ongoing chest compressions will be recorded over 2 minutes and average measurements will be noted.

The tidal volume required to achieve a visible chest rise will be considered the ideal tidal volume of that patient.

The ideal tidal volume will be compared with the average tidal volume delivered by adult and pediatric self-inflating bags.

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Pediatric self-inflating bag, adult self-inflating bag

**Primary outcome(s)**

To compare the inspired and expired tidal volumes delivered using an adult self-inflating bag with that of the pediatric self-inflating bag during cardiopulmonary resuscitation of adults

**Key secondary outcome(s)**

To estimate the average tidal volume required to achieve a visible chest rise over 1 second in adult cardiac arrest patients

**Completion date**

07/01/2024

**Eligibility****Key inclusion criteria**

Intubated adult (> 18 years) cardiac arrest patients undergoing cardiopulmonary resuscitation in the Emergency Department

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

99 years

**Sex**

All

**Total final enrolment**

130

**Key exclusion criteria**

1. Pregnant women
2. Bleeding or secretions in the endotracheal tube
3. Non-availability of flow analyzer

**Date of first enrolment**

10/10/2022

**Date of final enrolment**

20/12/2023

## Locations

**Countries of recruitment**

India

**Study participating centre**

Jawaharlal Institute of Postgraduate Medical Education and Research  
JIPMER Campus Rd, Gorimedu  
Dhanvantari Nagar  
Puducherry  
India  
605006

## Sponsor information

**Organisation**

Jawaharlal Institute of Post Graduate Medical Education and Research

**ROR**

<https://ror.org/02fq2px14>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Jawaharlal Institute Of Postgraduate Medical Education and Research

**Alternative Name(s)**

JIPMER

## Funding Body Type

Government organisation

## Funding Body Subtype

Local government

## Location

India

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Kowsthubha B G, jr7374@jipmer.ac.in. The data available are the patient details, diagnosis and volume metrics while using adult and pediatric self-inflating bags.

In this study, the rapidity with which the treatment is needed for cardiac arrest precludes obtaining consent from family members/ bystanders/ legally authorized representatives Also, considering the emotional stress state of grieving family members and/ or next of kin, seeking informed consent when CPR is in progress seems impractical, if not impossible. Hence the study can only be conducted with a waiver of informed consent.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other unpublished results</a>			30/12/2024	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes