ISRCTN10909864 https://doi.org/10.1186/ISRCTN10909864

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

Submission date
12/12/2023

Recruitment status
No longer recruiting

Registration date
20/12/2023

Overall study status
Completed

Last Edited
30/12/2024

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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)

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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
Participant information can be found at: https://docs.google.com/forms/d/e/1FAIpQLSdWFKYKCJSt8khU-8CZCowKJJJ0Sn3JbfCs6dvIEvC9JGr8dg/viewform?usp=sf_link

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Pediatric self-inflating bag, adult self-inflating bag

Primary outcome measure
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

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

Overall study start date
01/08/2022

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
130

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
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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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
07/06/2024

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?
Other unpublished results			30/12/2024	No	No