Final Study Protocol (retrospective documentation)

Official title	Impact of Two Resuscitation Sequences on Alveolar Ventilation during the First Minute of Simulated Pediatric Cardiac Arrest: Randomized Cross-Over Trial
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Transparency statement

This document was created retrospectively to describe the study design and statistical analysis used in the trial identified as NCT05474170. A single, formally finalized study protocol did not exist prior to study initiation. The contents of this document reflect the methods actually used and reported in the final published article (Suppan et al., Healthcare 2022).

Background and Rationale

Pediatric cardiac arrest resuscitation methods vary internationally, with differing guideline recommendations on the optimal sequence of initial interventions. The impact of these sequences on alveolar ventilation during the first minute of resuscitation remains unclear. This study was conducted to compare two commonly considered resuscitation sequences in a controlled simulation setting, with the primary interest in the ventilation outcome during the earliest phase of resuscitation.

Study Objectives

Primary Objective

To compare alveolar ventilation achieved during the first minute of simulated pediatric cardiac arrest between two resuscitation sequences.

Secondary Objectives

Secondary measures include additional ventilation and compression performance metrics as detailed in the published article.

Study Design

This was a randomized, cross-over simulation trial. Participants conducted resuscitation in a manikin simulation under two different resuscitation sequences. Each team performed both sequences, with order randomized.

- **Design Type:** Randomized cross-over
- **Setting:** Simulation laboratory
- **Duration:** Single session (of 2 scenarios) per team

Participants

Population

Teams of two individuals trained in pediatric resuscitation methods were enrolled. Inclusion and exclusion criteria were specified in the Methods section of the full text.

Interventions

The order in which teams performed these sequences was randomized. The wwo resuscitation sequences compared were:

- Sequence A: Initial ventilations followed by chest compressions (ERC ventilation-first sequence)

Participants initiated resuscitation with five initial rescue breaths, in accordance with European Resuscitation Council recommendations for pediatric cardiac arrest. After delivery of the five initial ventilations, participants proceeded with cycles of 15 chest compressions followed by 2 ventilations. This 15:2 compression-to-ventilation ratio was maintained during the first minute of resuscitation. The objective of this sequence was to prioritize early oxygen delivery through ventilation before initiating chest compressions.

- Sequence B: Chest compressions first (AHA compression-first sequence)

Participants initiated resuscitation immediately with **chest compressions**, without delivering initial rescue breaths, in accordance with American Heart Association recommendations for pediatric cardiac arrest. Compressions were delivered according to pediatric resuscitation guidelines, followed by ventilations in 15 compressions to 2 ventilations (15:2) ratio. No initial series of rescue breaths was provided before the first compression cycle. The objective of this sequence was to prioritize immediate circulatory support.

Outcome Measures

Primary outcome

Alveolar ventilation during the first minute of simulated pediatric cardiac arrest.

Secondary outcomes

Additional measures (e.g., chest compression parameters, ventilation metrics) as reported in the article.

All outcomes are defined and measured as detailed in the article's Methods section.

Statistical Analysis

Data from all randomized teams were included in analysis. Statistical methods employed reflected the cross-over design of the study.

- Data were analyzed using appropriate comparative statistics for cross-over studies.
- Descriptive and inferential statistics were conducted as reported in the published Methods.
- No formal separate Statistical Analysis Plan existed; methods were those implemented and reported.

Ethics and approvals

The Swiss Federal Law on Human Research does not apply to this kind of project as no health outcomes are assessed among participants and because the participants do not belong to a vulnerable population. A clarification of responsibility (Req #2022-00810) was nevertheless requested from the regional Ethics Committee (CCER—Commission Cantonale d'Ethique de la Recherche sur l'être humain, Geneva, Switzerland). All included participants provided electronic informed consent.

Data management

Data were automatically collected through the manikin's sensors, thereby preventing assessment bias. All the variables of interest listed above were automatically generated using a custom-coded hypertext pre-processor (PHP) script. These variables were then exported to a comma-separated values (CSV) file and imported for statistical analysis in Stata 15.1 (StataCorp, LLC, College Station, TX, USA). All authors had access to the database. The curated dataset is publicly available on Yareta

Publication

Suppan L, Jampen L, Siebert JN, Zünd S, Stuby L, Ozainne F. Impact of Two Resuscitation Sequences on Alveolar Ventilation during the First Minute of Simulated Pediatric Cardiac Arrest: Randomized Cross-Over Trial. Healthcare. 2022; 10(12):2451. https://doi.org/10.3390/healthcare10122451