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Respiratory Gas Shifts to Delay Asphyxiation in Critical Avalanche Burial A Randomized Clinical Trial

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IMPORTANCE People who are critically buried by an avalanche typically die of asphyxia within 35 minutes, often making timely rescue impossible. The development of new strategies to delay asphyxiation is crucial to improve survival rates.

OBJECTIVE To investigate the efficacy of a novel, user-carried avalanche safety device that delivers airflow from avalanche debris to the user's airway without requiring supplemental oxygen or a mouthpiece.

DESIGN, SETTING, AND PARTICIPANTS This randomized, blinded, clinical trial was organized by 4 institutions and conducted at 1 field location in Italy from January to March 2023. Healthy volunteers aged 18 to 60 years were enrolled. Trial participants underwent a critical snow burial simulation while in a prone position covered by at least 50 cm of snow. Vital parameters were continuously monitored throughout the simulation to ensure participant safety and to collect physiological data.

INTERVENTIONS Participants were randomized to the safety device group (using the Safeback SBX device) or the control group (using a sham device). The safety device group completed an unblinded control in which the participants who remained buried after 35 minutes were seamlessly transferred to the sham device.

MAIN OUTCOMES AND MEASURES The primary outcome measure was the time to oxygen saturation as measured by pulse oximetry (SpO_2) less than 80% (event) during 35 minutes of monitoring, comparing intervention and control groups. Secondary outcomes included oxygen and carbon dioxide concentrations at different distances in the snow.

RESULTS Of 36 randomized participants, 24 performed and completed the trial and were included in the final analysis. The median (IQR) age was 27 (25-32) years, and 13 (54%) were male. In the safety device group, the median (IQR) burial duration was 35.0 (35.0-35.0) minutes and there were no events; in the control group, the median (IQR) burial duration was 6.4 (4.8-13.5) minutes and there were 7 events. The safety device group had a significantly lower risk of termination due to SpO_2 less than 80% ($P < .001$ for both log-rank and Breslow tests). Carbon dioxide in the air pocket was 1.3% (95% CI, 1.0%-1.6%) vs 6.1% (95% CI, 5.1%-7.1%) and oxygen was 19.8% (95% CI, 19.5%-20.1%) vs 12.4% (95% CI, 11.2%-13.5%) at the same points in the safety device and control groups, respectively.

CONCLUSIONS AND RELEVANCE A user-carried avalanche safety device that delivers airflow from avalanche debris to the user's airways without requiring supplemental oxygen delayed critical hypoxemia and hypercapnia during simulated critical burial.

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Avalanches are a significant natural hazard in snow-covered mountain regions worldwide, claiming the lives of many winter recreationists.¹ Critical snow burial (defined as head and chest covered by snow) is associated with a fatality rate of 50%.² Devices that cause an inverse segregation effect (ie, the larger particles in the flow are sorted toward the surface), such as an inflated airbag, decrease mortality because they reduce the risk of complete burial.³

However, the onset of hypercapnia, hypoxemia, and hemodynamic instability are the main mechanisms limiting survival in individuals critically buried in an avalanche.⁴ These changes develop progressively within minutes.⁵⁻⁷ Prior data suggest that approximately two-thirds of individuals critically buried in an avalanche die of asphyxia within the first 35 minutes due to cardiac arrest from asphyxiation, with a decrease in the probability of survival beginning at 10 minutes of burial.⁸⁻¹¹

The prevention or delay of the onset of hypoxemia and hypercapnia may extend survival time, allowing companions and rescue teams to arrive in time to extract the buried individual alive. Two studies suggest that an artificial air pocket device, designed to separate exhaled air from inhaled air, can prolong survival if properly used,^{6,7} but usability of the device has limited its wide distribution. Those critically buried by an avalanche can also use oxygen entrapped in the snow,^{5,12} particularly low-density snow.⁵ The development of hypercapnia in buried people can also be mitigated by receiving supplemental air with flows as low as 2 L per minute.¹³ Based on these observations, a device was designed to actively draw air through an intake located on the backpack and channel this toward the individual's face.

This study investigated the efficacy of this user-carried device specifically designed to deliver airflow from avalanche debris toward airways, without requiring additional oxygen or a mouthpiece, during simulated critical snow burial. Further analyses evaluated changes in respiratory and cardiovascular responses and the distribution and flow of gases in avalanche debris.

Methods

Trial Oversight

This interventional, randomized, clinical, double-blind trial was approved by the Ethics Committee for Clinical Trials and Testing of Bolzano, Italy (protocol No. 6-2023) and registered with ClinicalTrials.gov (NCT05779540). The study was conducted in adherence to the Declaration of Helsinki¹⁴ and followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.¹⁵ The study was performed in Italy from January to March 2023.

Participants

The recruited participants were healthy adult volunteers aged 18 to 60 years classified according to the American Society of Anesthesiologists (ASA) as ASA 1.¹⁶ Only participants providing written informed consent were eligible. We excluded participants with any acute disease on the trial day or a claustrophobia questionnaire score greater than or equal to 35 (eFigure 1 in Supplement 2).¹⁷ Participant race was determined by the researcher based on fixed categories, and was collected because of differing physiologic responses to hypoxia. No remuneration was provided except for reimbursement of travel and accommodation expenses.

Key Points

Question Does a novel device delay the onset of hypoxemia and hypercapnia during critical avalanche burial by enhancing airflow to users' airways?

Findings Median burial durations were 35.0 minutes in the intervention group, with no events (defined as $SpO_2 < 80\%$), and 6.4 minutes in the control group, with 7 events. The device demonstrated its efficacy in simulated burial scenarios delaying hypoxemia and hypercapnia, and stabilizing ventilatory and cardiovascular parameters.

Meaning Integrating this innovative technology into personal avalanche safety equipment, alongside existing tools like avalanche airbags and transceivers, could increase survival rates by extending the time available for successful rescue.

phobia questionnaire score greater than or equal to 35 (eFigure 1 in Supplement 2).¹⁷ Participant race was determined by the researcher based on fixed categories, and was collected because of differing physiologic responses to hypoxia. No remuneration was provided except for reimbursement of travel and accommodation expenses.

System Description

The Safeback SBX (Safeback SE) is a device classified as a level II personal protective equipment in the European Union. When activated via a T-shaped handle, the device draws in ambient air from the snow surrounding the backpack by a fan and delivers it to bilateral air outlets located in the upper chest area. These outlets direct the air with a flow rate of approximately 150 L per minute from avalanche debris to the user's airways. The manufacturer guarantees that the fan, powered by AA batteries, maintains a run time of at least 60 minutes, even at temperatures as low as $-30\text{ }^\circ\text{C}$. The fan is intentionally oversized to ensure that airflow remains sufficient to support ventilation up to 90 minutes.

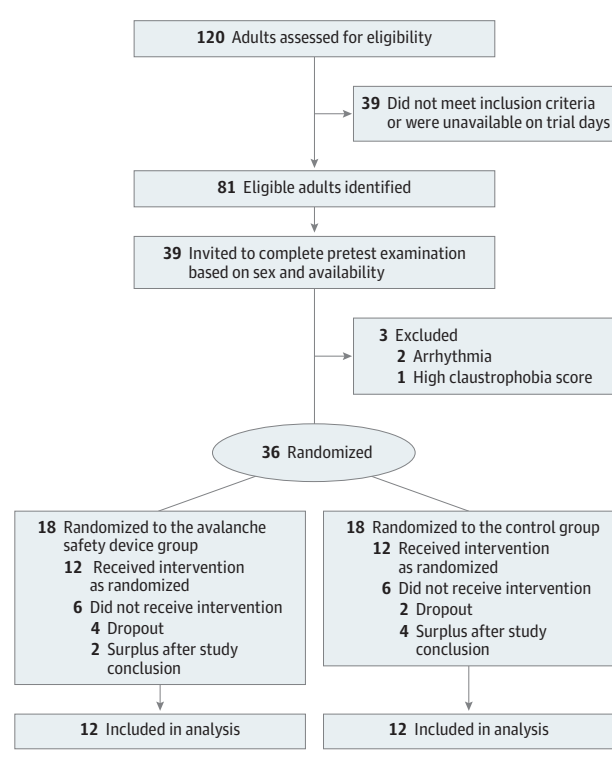
Trial Procedures

The participants were randomly assigned to either the intervention (avalanche safety device) or the control group using a stratified randomization per day generated by a statistician using R software version 4.1.1 (R Foundation),¹⁸ randomizing 4 participants per day (2 to the intervention group and 2 to the control group). A modified sham device was used as a control; it emitted noise identical to the active device but delivered no airflow. The study team, except for the principal investigator (G.S.) responsible for safety and managing the switch process, was blinded to group randomization.

Participants were buried in a prone position with their head and chest under simulated avalanche debris at a depth larger than 50 cm, sufficient to simulate the challenges of snow burial while minimizing the risk to participants (eFigures 2 and 3 in Supplement 2).^{6,7} Each participant underwent 1 trial (either intervention or control) for a maximum of 60 minutes and remained blinded to the group assignment. The experimental setup is shown in eFigure 8A in Supplement 2.

During the trial, peripheral oxygen saturation as measured by pulse oximetry (SpO_2), end-tidal carbon dioxide

Figure 1. Recruitment, Randomization, and Participant Flow



All participants presenting on test days completed the full study protocol. Once the predefined target of 24 participants (12 per group) completed the study, the remaining participants were excluded prior to the trial.

^aSex-based invitation aimed to balance groups; availability considered scheduling and avoiding excessive travel distances.

^bClaustrophobia score ≥ 35 predicts clinically significant claustrophobia.¹⁷

(ETCO₂), and heart rate (HR) were continuously measured (Supplement 2). Ventilation parameters including respiratory rate, tidal volume (V_T), and minute ventilation (\dot{V}_E) (ExSpirom 2Xi system [Respiratory Motion Inc]), regional cerebral oxygen saturation (rSO₂) (Masimo O₃ regional oximetry [Masimo Corporation]), and the cardiac index (ICON Electrical Cardiometry system [Osypka Medical GmbH]) were also measured. Devices with a sampling rate higher than 1 measurement per second were interpolated to obtain 1 measurement per second.

Float probes for gas measurement were placed in the surrounding snowpack according to a predefined scheme (eFigure 8A in Supplement 2) and gas concentrations (ie, oxygen and carbon dioxide fractions) were measured (Dräger X-AM 7000/8000 [Dräger Safety AG]). Snow characteristics were measured from the base and the lateral wall near the air pocket before each trial (Supplement 2). Trials were terminated if the participant had Spo₂ less than 80% (defined as an event) or voluntarily on participant request (by pulling a rope attached to the hand or by radio).

Trials in the control group ended after a maximum burial time of 35 minutes. When a participant randomized to the safety device group (with avalanche safety device running) clocked a time of 35 minutes, the avalanche safety device was

Table. Participant Characteristics

Characteristic	Intervention (n = 12)	Control (n = 12)
Age, median (range), y	28 (24-54)	27 (23-41)
Female sex, No. (%)	7 (58)	4 (33)
Male sex, No. (%)	5 (42)	8 (67)
Body mass index, mean (SD)	21.0 (2.1)	23.7 (2.0)
FVC, mean (SD), % of predicted ^a	96.3 (7.5)	100.2 (6.1)
FEV1, mean (SD), % of predicted ^a	97.1 (7.1)	106.7 (9.2)
DLCO, mean (SD), % of predicted ^a	129.2 (12.4)	133.7 (19.4)
TLC, mean (SD), % of predicted ^a	94.7 (11.2)	99.3 (7.9)
Claustrophobia score, median (IQR) ^b	2 (0-23)	5 (0-13)

Abbreviations: DLCO, diffusing capacity of the lungs for carbon monoxide; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; TLC, total lung capacity.

^a Predicted values per EasyOne Pro default (nidd Medical Technologies).

^b Claustrophobia scores were assessed using the Claustrophobia Questionnaire, and could range from 0 to 96. A score of 35 or higher was considered predictive of clinically significant claustrophobia.¹⁷

switched off and the sham device was activated simultaneously by remote control (unblinded control; eFigure 8B in Supplement 2). After the switch-off procedure, the trial was terminated when Spo₂ less than 80% was reached, after a maximum of an additional 25 minutes, or on the participant's request.

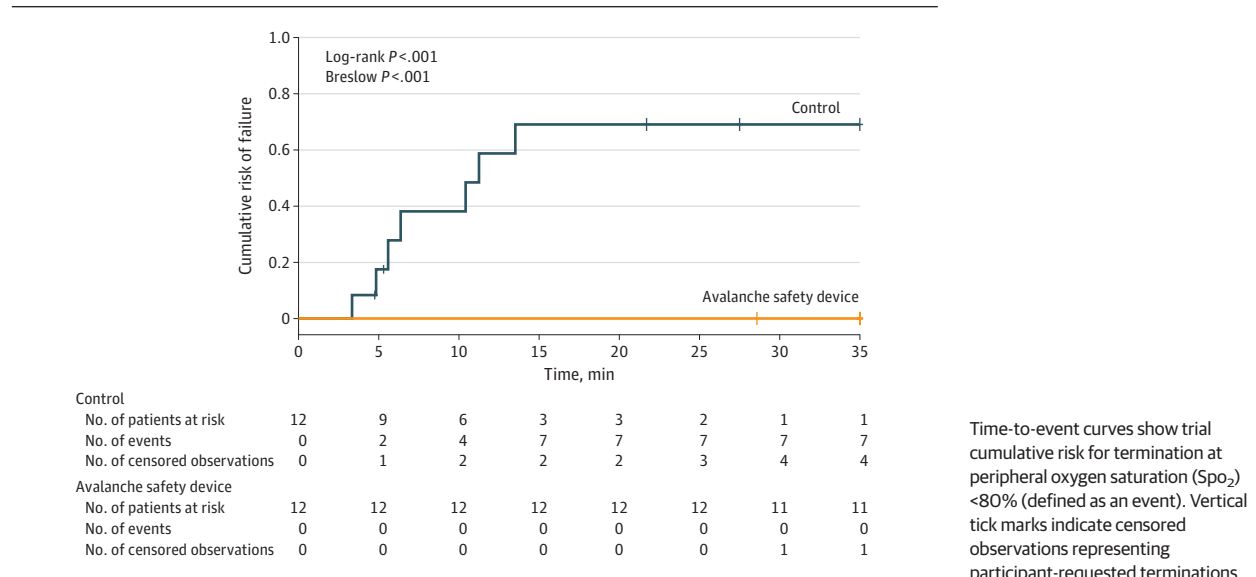
Study Outcomes

The primary outcome of the study was the time from burial to trial termination, defined as Spo₂ less than 80%. There were 17 secondary outcomes of the study. These included changes from burial to trial termination in oxygen saturation (Spo₂, rSO₂), end-tidal carbon dioxide (etCO₂), ventilatory (respiratory rate, V_T , \dot{V}_E) and cardiovascular parameters (HR and cardiac index), oxygen and carbon dioxide fraction at different distances (air pocket and backpack air outlets 25 and 50 cm from air pocket), and time from switching off the device to termination at Spo₂ less than 80% during the unblinded control extension.

Statistical Analysis

A sample size for time-to-event data and a parallel group design was calculated based on defined assumptions. Assuming a hazard ratio of 0.25, an α of .05, and statistical power of 80%, a total of 17 events would be needed to confirm a statistically significant difference between the groups. From earlier trials and an initial pilot test, we assumed a baseline event rate of 0.85 and a censoring rate of 0.15. The total sample size was calculated to be 24 participants, with 12 participants per group. Due to the time and organizational demands of the study protocol, 36 participants were recruited and randomized to intervention (avalanche safety device) and control groups. Once the predefined target of 24 participants (12 per group) completed the study, the remaining participants were excluded

Figure 2. Kaplan-Meier Analysis of Cumulative Risk for Termination at SpO₂ Less Than 80% in Control and Intervention Group



prior to the trial. Selection for final analysis therefore occurred randomly based on the assigned test day and attendance.

Descriptive methods were used to characterize the sample. The primary outcome was analyzed using Kaplan-Meier curves and log-rank and Breslow tests were used to compare time from burial to trial termination at SpO₂ less than 80% (defined as an event) between the safety device and control group as well as for sensitivity analyses of the primary outcome. The unblinded extension of the intervention group after crossover was analyzed similarly vs participants in the control group. For time-dependent variables, an analysis of covariance for each point (second) after baseline was performed,^{13,19} adjusting for baseline measurement. The point when the 95% CI for coefficient β of the analysis of covariance did not contain the value 0 for at least 30 seconds was considered to determine the point when intervention and control curves differed. In the graphics, mean curves were drawn until data of at least 4 participants were available (in the control group this was at 13 minutes and 31 seconds for all parameters, except etCO₂ and cardiac index, for which it was at 11 minutes and 15 seconds because of missing values) and this point of the control curve was used for comparison of parameters between the intervention and the control groups. An independent sample *t* test was used to compare snow density between the intervention and control groups. Normal distribution was assessed by means of the Shapiro-Wilk test and quantile-quantile plots. Values are reported as mean (SD) if normally distributed and as median (IQR) otherwise. A 2-sided *P* value of .05 was considered statistically significant. The statistical analysis was conducted using R software version 4.1.1 (R Foundation),¹⁷ and the graphics were derived using Matlab 9.8.0 (MathWorks).²⁰

Results

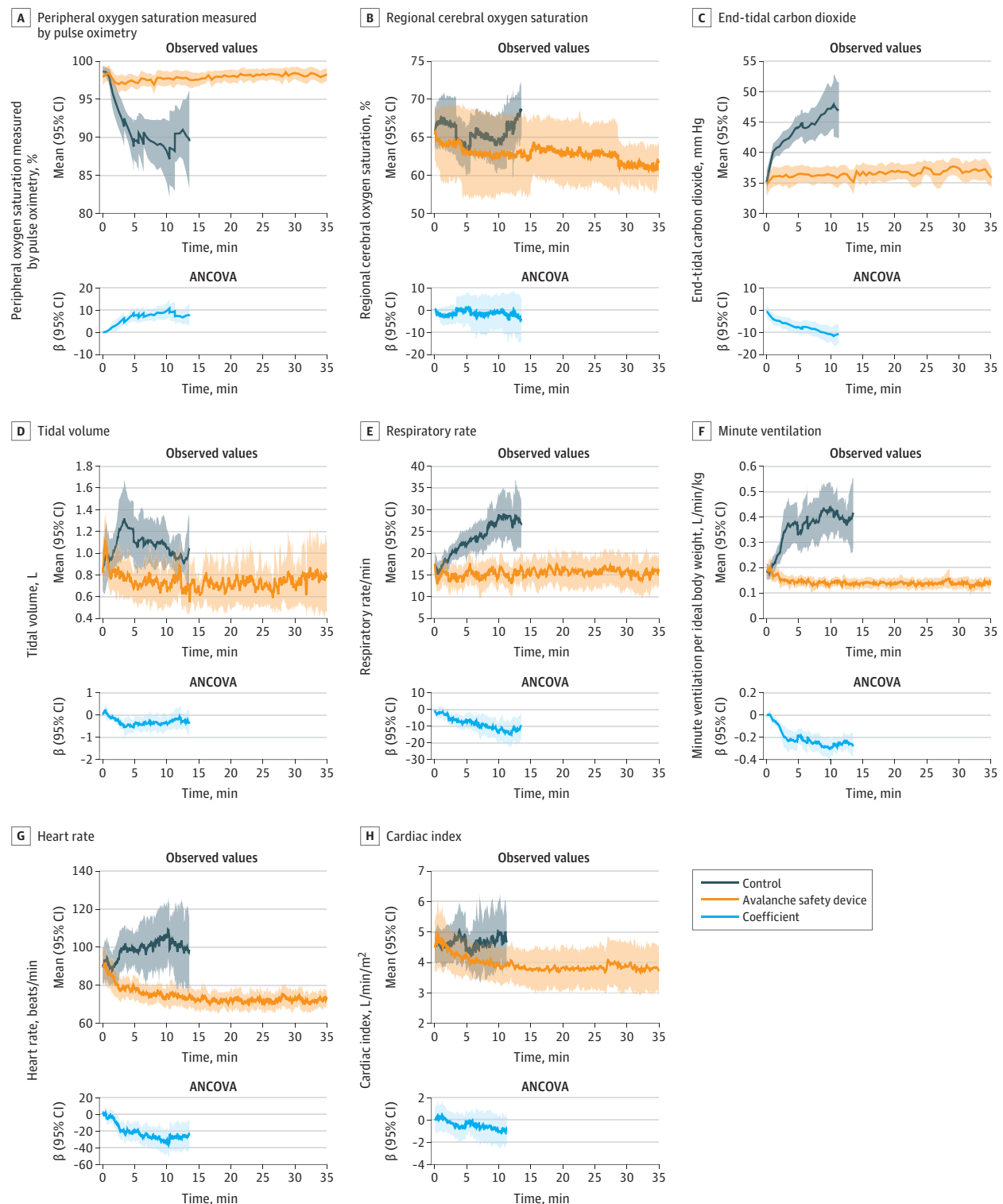
Main Characteristics

Of 120 volunteers assessed for eligibility, 36 were consecutively enrolled in the study (Figure 1). Of these individuals, 6 did not attend on trial days and 6 were excluded once the pre-defined target of 24 participants was reached. Twenty-four participants (12 per group; median [IQR] age, 27 [25-32] years; 11 [46%] female; 24 identified as White race) completed the trial and were included in the final analysis (Table). Overall mean (SD) snow density was 496 (30) kg/m³ (mean [SD] of 488 [34] kg/m³ in the safety device group vs 504 [26] kg/m³ in the control group; *P* = .22; eTable in Supplement 2).

Primary Outcome

In the avalanche safety device group, 11 participants completed the maximum trial duration of 35 minutes, while 1 requested early termination due to transient upper extremity paresthesia. In the control group, only 1 participant completed the full 35-minute trial, while 11 terminated early. Of these 11 trials that were ended early, 7 were stopped at SpO₂ less than 80% and 4 were terminated at participant request (3 due to dyspnea and 1 due to a panic attack). The median (IQR) burial duration was 35.0 (35.0-35.0) minutes in the safety device group and 6.4 (4.8-13.5) minutes in the control group. The cumulative risk for termination at SpO₂ less than 80% was lower in the safety device group than in the control (*P* < .001 for both log-rank and Breslow tests; Figure 2). There were no events observed in the intervention group. Median time to event for the control group was 11.2 (95% CI, 5.6 to not applicable [where not applicable indicates that the upper confidence limit could not be estimated due to the limited number of events or censored observations beyond this point]). A sensitivity analysis

Figure 3. Temporal Trends in Oxygenation, Ventilation, and Hemodynamic Parameters



A detailed visualization of first and last measurements, including individual data points and corresponding boxplots, is provided in eFigure 7 in Supplement 2. ANCOVA indicates analysis of covariance.

for the primary outcome showed a lower cumulative risk for termination in the safety device group than in the control ($P < .001$ for both log-rank and Breslow tests; eFigure 4A in Supplement 2).

Secondary Outcomes

Oxygenation, ventilation, and cardiovascular parameters of each trial are shown in **Figure 3** and **eFigure 7** in **Supplement 2**. In the safety device group vs the control group, SpO_2 was 98% (95% CI, 96%-99%) vs 89% (95% CI, 83%-96%), rSO_2 was 63% (95% CI, 57%-68%) vs 68% (95% CI, 65%-72%), and $etCO_2$ was 36 (95% CI, 34-38) mm Hg vs 47 (95% CI, 42-52) mm Hg. Also at the same points in the safety device vs control group, \dot{V}_E/IBW was 0.14 (95% CI, 0.11-0.16) L/min/kg vs 0.42 (95% CI, 0.28-0.55) L/min/kg, respiratory rate was 17 (95% CI, 13-30) breaths/min vs 27 (95% CI, 22-32) breaths/min, V_T was 0.7 (95% CI, 0.5-0.9) L vs 1.0 (95% CI, 0.7-1.4) L, HR was 74 (95% CI, 68-80) bpm vs 99 (95% CI, 79-119) bpm, and cardiac index was 3.9 (95% CI, 3.3-4.5) L/min/m² vs 4.7 (95% CI, 3.8-5.7) L/min/m².

Gas concentrations for each trial are shown in **eFigures 5** and **6** in **Supplement 2**. Carbon dioxide concentrations in the air pocket in the safety device vs control group were 1.3% (95% CI, 1.0%-1.6%) vs 6.1% (95% CI, 5.1%-7.1%), while oxygen concentrations were 19.8% (95% CI, 19.5%-20.1%) vs 12.4% (95% CI, 11.2%-13.5%) at the same points. Conversely, at 50 cm from the air pocket, carbon dioxide and oxygen showed minimal variation in the control group, while carbon dioxide increased and oxygen decreased in the intervention group (**eFigure 9** in **Supplement 2**).

In the unblinded control phase after crossover, 11 participants in the intervention group terminated trial burial at a median (IQR) of 7.2 (5.6-15.3) minutes (**eFigure 4B** in **Supplement 2**).

Discussion

In this randomized, blinded, clinical trial of healthy adult volunteers, the investigated avalanche safety device effectively delayed the onset of hypoxemia and hypercapnia in prone participants critically buried under simulated avalanche debris. The influx of fresh air removed exhaled carbon dioxide from the air pocket, increased participant measures of oxygenation, and maintained stable respiratory and cardiovascular parameters for up to 35 minutes.

Asphyxia accounts for approximately 75% of fatalities following critical avalanches burial,^{4,21} while trauma is responsible for less than 20%.^{9,22,23} As such, the avoidance of hypoxia and hypercapnia is an imperative to increase survival probability. People critically buried by an avalanche with a patent airway²⁴ can use the oxygen entrapped in the snow,⁵ and there is a favorable effect of low-density snow and airflow for advection of respiratory gases.^{5,13} In this study, a significant and rapid decrease was observed in fraction of inspired oxygen (FiO_2) of approximately 13% and an increase in fraction of inspired carbon dioxide ($FiCO_2$) of greater than 5% within 5 minutes of burial in the control group, consistent with previous studies.^{5-7,13,25} This can be explained by the advection of gas in the porous structure of avalanche debris. This study extends prior work by demonstrating improved gas flow despite the high snow density (500 kg/m³). Results also show that the decreases in FiO_2 and increases in $FiCO_2$ triggered strong

compensatory ventilatory and cardiovascular responses, marked by rapid increases in respiratory rate, V_T , \dot{V}_E , HR and cardiac index, confirming data of previous studies.^{4-7,13,25-28} In the safety device group, the absence of a decreased FiO_2 and an increased $FiCO_2$ blunted any ventilatory and cardiovascular responses.

The window for successful rescue of an individual critically buried by an avalanche is as short as 10 minutes,^{10,11} and the survival probability drops from 91% to 31% by 35 minutes.¹¹ This device is among a suite of options to improve survival in avalanche burial. First, airbags with an inverse segregation effect prevent burial and may reduce the risk of critical burial by 27% when inflated.^{3,29,30} Second, avalanche transceivers shorten the duration of burial by allowing location and early extrication of the buried individual.³¹ Third, artificial air pocket devices allow a critically buried individual to breathe under the snow with sufficient oxygenation and elimination of carbon dioxide,^{6,7} but usability of the device has limited its wide distribution. The current study now demonstrates the efficacy of a device designed to deliver airflow from avalanche debris toward the user's airways without the need for additional oxygen or a mouthpiece. To date, these devices are not tested in combination^{2,21} nor do they replace preventive measures, which include education and training, knowledge of the avalanche bulletin, and increased awareness of the importance of risk-taking behaviors and other human factors in avalanche safety.^{21,29,32,33}

An important aspect of the study design was the unblinded control phase. This approach sought to investigate potential bias such as differences in the setup and accidental airflow. The device was deactivated after 35 minutes in the intervention group. The cumulative risk of termination and the measurements of oxygenation, ventilation, FiO_2 , and $FiCO_2$ showed no differences compared with the control group. These data support the robustness of the experimental design and the effectiveness of the device.

Limitations

This study has limitations. First, the trial used a simulated critical burial, and the results may not be entirely generalizable to real-world conditions. Second, the study did not examine critical asphyxia, but used surrogate outcome measures of critical hypoxia and hypercapnia. Third, the simulation used a single depth of 50 cm informed by actual avalanche data, which typically reach 80 cm.¹⁰ Results may vary at different depths. Fourth, the obstruction of the outlet and inlet may also differ in real-world burial. However, manufacturer tests demonstrated a power of 70% and inlet/outlet obstruction of 50% of the airflow of 100 L/min. Restriction of chest movement or various snowpack weights were not tested.

Conclusions

A user-carried avalanche safety device that delivers airflow from avalanche debris to the user's airways without requiring supplemental oxygen delayed critical hypoxemia and hypercapnia during simulated critical burial.

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Author Contributions: Dr Strapazzon had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Eisendle, Roveri, Rauch, Thomassen, Assmus, Malacrida, Kammerer, Schweizer, Falk, Falla, Wallner, Brattebø, Brugger, Strapazzon.

Acquisition, analysis, or interpretation of data: Eisendle, Roveri, Rauch, Thomassen, Dal Cappello, Assmus, Kammerer, Borasio, Dörck, Falk, Fruzzetti, Maxenti, Mydske, Sasso, Vinetti, Wallner, Brattebø, Strapazzon.

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Statistical analysis: Eisendle, Dal Cappello, Assmus, Dörck, Falk, Strapazzon.

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Administrative, technical, or material support: Eisendle, Roveri, Rauch, Thomassen, Kammerer, Dörck, Falla, Fruzzetti, Maxenti, Mydske, Sasso, Vinetti, Wallner, Brattebø, Strapazzon.

Supervision: Sasso, Wallner, Brugger, Strapazzon.
Other - field experiments: snow characterization: Schweizer.

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Role of the Funder/Sponsor: The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication. Safeback SE had no role in the data analysis, manuscript writing, or any other aspects of the research process; one of the authors are financially involved in the production or sale of the device, nor have they received any related grants or patents.

Data Sharing Statement: See Supplement 3.

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