Feedback devices may not improve chest compression depth during simulated out-of-hospital cardiac arrest: a multicenter randomized controlled trial

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Abstract

Out-of-hospital cardiac arrest survival remains low, with high-quality Cardiopulmonary Resuscitation (CPR) essential to improving outcomes. The i-gel® device allows continuous compressions but has been associated with reduced compression depth. While real-time feedback devices can improve CPR quality, their effectiveness alongside supraglottic airways remains untested. This multicenter, randomized, simulation-based superiority trial evaluated whether using a feedback device during CPR with i-gel® improves the proportion of compressions within the recommended depth range (5-6 cm). Between January and June 2023, 68 participants from eight EMS agencies formed 34 teams, randomized to either control (no feedback) or experimental (with feedback). All teams performed 10-minute adult CPR scenarios on a manikin in ventricular fibrillation, with immediate i-gel® insertion. The primary outcome was the proportion of compressions within the target depth range of 5 to 6 cm. Secondary outcomes included usual CPR and ventilation metrics. No significant differences were found in correct compression depth between control and feedback group (68.6% [95%CI 57.2-80.1] vs 60.5% [95%CI 50.5-70.5]). However, chest recoil was significantly better in the control group (95.9% *vs* 90.2%, p=0.024). Other CPR and ventilation metrics did not differ significantly. In conclusion, the feedback device did not significantly improve compression depth and was associated with slightly worse chest recoil.

Introduction

Out-of-Hospital Cardiac Arrest (OHCA) remains a significant challenge, with low survival rates despite advances in emergency care. High-quality Cardiopulmonary Resuscitation (CPR), especially chest compressions within the recommended depth and rate, is critical for improving patient outcomes.[1,2] However, maintaining these standards can be challenging in the prehospital setting, where other priorities, such as airway management, compete for attention.

OHCA airway management approaches vary, including Bag-Valve-Mask (BVM) ventilation, Supraglottic Airways (SGA), and endotracheal intubation.[3,4] Each of these methods has unique benefits and limitations regarding ease of use, effectiveness, and impact on chest compressions. BVM ventilation is often ineffective during early CPR before more advanced airway management is applied.[5,6] Intermediate[7] and advanced airway management devices, such as the i-gel® SGA device, offer potential advantages in increasing Chest Compression Fraction (CCF) by enabling continuous compressions with fewer interruptions.[8,9] Intermediate air-

way management likely leads to increased rates of Return Of Spontaneous Circulation (ROSC) and faster time to airway placement, while its effect on longer-term survival outcomes or aspiration events may be limited.[10] One of our previous studies suggests that early i-gel® use significantly improves CCF and ventilatory parameters but may reduce compression depth,[11] an important determinant of survival and functional outcome.[12] Additionally, research highlights a discrepancy between perceived and actual CPR performance, underscoring the value of real-time feedback to bridge this gap.[13,14] By guiding providers in maintaining compressions within optimal depth and rate ranges, feedback devices could enhance CPR quality. Studies indicate contradictory impacts of CPR feedback devices. While some report no improvement in CPR quality and an association with a higher percentage of overly deep compressions,[15] others have found improved patient outcomes.[16] Feedback devices in the prehospital setting have been associated with improved guideline compliance for CPR metrics but not with outcomes such as ROSC, sustained ROSC, or survival to hospital discharge.[17-19] These devices could play a role in encouraging deeper compressions and helping maintain compressions within target parameters,[17,20-25] potentially offsetting the depth reduction related to i-gel® use.

This study investigated whether a feedback device could address the issue of shallower chest compression depth associated with the use of an i-gel® device during CPR.

Materials and Methods

Study design, ethics, and setting

This was a multicenter, randomized superiority study based on a simulated model of OHCA conducted between January and June 2023. The study was registered at ClinicalTrials.gov (NCT0570961) and submitted to the regional Ethics Committee (Req-2023-00021), which waived approval as the study did not fall within the scope of Swiss federal law on human research. This manuscript complies with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[26] The trial was carried out according to the principles of the Declaration of Helsinki and the Good Clinical Practice guidelines. Participation was voluntary, no incentive was provided, and participants could withdraw at any time without providing justification.

In Switzerland, the organization of prehospital Emergency Medical Services (EMS) varies by canton due to a decentralized healthcare system. Paramedics, who complete a three-year training program, typically lead prehospital care. In some cantons, paramedics may be assisted by Emergency Medical Technicians (EMTs), who undergo a one-year training program. Depending on the canton, nurses may replace EMTs or paramedics. In critical cases, additional mobile medical support units (*Service Mobile d'Urgence et de Réanimation* - SMUR), may also be dispatched. These units are staffed with an emergency physician and a paramedic or a specialized nurse. Helicopter Emergency Medical Services (HEMS), operated by a pilot, an emergency physician, and a paramedic, are also available in certain settings.

In many regions, first responders – volunteer healthcare professionals or trained laypeople – are dispatched based on their proximity to the location of an OHCA using an application-based alarm system to ensure a rapid response. EMS treatment protocols vary across cantons and even between local EMS as they are overseen by the local EMS medical director.

Recruitment

Paramedics and EMTs employed at any of the 8 participating centers in the study were eligible to participate. The only exclusion criterion was being a member of the study team. Participants were recruited by a local coordinator via a standardized email that provided detailed information about the study, including data protection policies. To minimize preparation bias, participants were blinded to the specific outcomes of the study, though they were informed that the focus was on OHCA management. Participants then logged in to the study platform, where their demographic data were collected, and electronic consent was obtained.

Randomization

Two levels of randomization were used. Each trial center represented a cluster, and teams were first randomized within each cluster using an online balanced team generator,[27] with stratification by professional status. To reflect current clinical practice, each team included at least one paramedic. In mixed teams (*i.e.*, paramedic and EMT), the paramedic always served as the team leader. In paramedic-only teams, the role of each paramedic was left to their discretion, as in actual clinical settings.

The second level of randomization took place just before the study scenario began. Teams were randomized to one of the two study arms by opening an opaque, sealed envelope created using a block randomization list generated online by LoS in a 1:1 ratio, with block sizes of 2 and 4, and stratification according to EMS centers.[28] This stratification accounted for differences in approach among participants, such as initial airway management strategy, task distribution, local procedures, quality processes, and prior specific training.

Self-managed training session

Each team had 15 minutes to self-train on the use of the i-gel® device within the entire OHCA management loop, using a CPR manikin equipped for airway management. A demonstration video[29] was provided to guide the training, and teams could refer to it as needed. Additionally, an overview of the simulation manikin's features and the defibrillator's use was given through a standardized video.[29]

Equipment

For each study session, the same human patient simulator and dedicated multiparametric monitor/defibrillator (Laerdal SimMan 3G, Laerdal Medical, Stavanger, Norway) were used. All other equipment required for the scenario was made available in standard service intervention bags, including placeholder medications (*e.g.*, sterile water). Teams were briefed on the location and characteristics of the equipment before the scenario and before randomization. A size 4 i-gel® device (Intersurgical Ltd., Wokingham, UK) and a lubricant were also provided in the intervention bag. The feedback device used was Real CPR Help® by ZOLL, connected to a dedicated ZOLL monitor positioned at the feet of the manikin. Chest compression feedback was displayed on this monitor rather than on the SimMan's due to technical incompatibilities.

Study scenario

Each team was asked to perform a 10-minute high-fidelity adult CPR scenario on the WiFi-enabled manikin. The scenario was identical across all sites to ensure consistency and minimize confounding variables. The simulation was conducted in a dedicated distraction-free room. Participants were informed that the sce-

nario would last 10 minutes, regardless of their actions, and that no feedback would be provided during the session.

The scenario began with a clinical statement: "*Here is Michael, a 50-year-old man who collapsed 10 minutes ago. He is now unconscious, pale, and appears not to be breathing. Medical reinforcement is on its way and will arrive in about ten minutes. No first responder was dispatched, and no bystanders are present*". The team leader was then asked to rephrase this statement to confirm understanding. Then, the leader opened an opaque, sealed envelope indicating group allocation (no feedback or feedback device). After this step, there was no further interaction with the study team until the scenario ended.

The simulated patient was apneic and pulseless. The first compression was considered as T0. After pad placement, the defibrillator showed a ventricular fibrillation (VF) rhythm. CPR waves were displayed during compressions, and all subsequent rhythm analyses showed refractory VF. Participants were provided with an i-gel® device and were able to establish intravenous access and to administer epinephrine and amiodarone. The scenario concluded precisely 10 minutes after the first compression.

Study groups

In the experimental group, the Real CPR Help® feedback device was already placed in the center of the chest by the investigators to ensure consistent positioning. It was left in place across all scenarios to minimize potential placement bias. This adhesive pad was connected to a ZOLL monitor placed at the simulated patient's feet, providing real-time feedback on chest compression quality. It is important to note that this monitor was distinct from those used to operate the manikin and was solely dedicated to providing feedback on compression quality. In the control group, the same setup was used, but the feedback monitor remained turned off throughout the simulation.

Outcomes

The primary outcome was the proportion of compressions within the target depth range (5 to 6 cm). Secondary outcomes included: overall CCF; average chest compression depth; proportion of compressions within the target rate (100 to 120 compressions per minute); average chest compression rate; proportion of compressions with complete chest recoil (defined as <5 mm deviation from the reference value); time to first effective ventilation (defined as >300 mL);[30-34] time to first defibrillation; number of defibrillation attempts; number of ventilations provided; effective minute ventilation, calculated as follows: the product of the mean ventilation volume and the number of ventilations, divided by the difference between 10 minutes and the time to the first ventilation; proportion of ventilations within target (300-700 mL).

Blinding and bias minimization

To minimize bias, group allocation was disclosed only after teams were introduced to the manikin, defibrillator, and scenario. Until that point, participants remained blinded during both the workshop and the self-managed training session. Following the allocation, no further interaction occurred with the investigators during the simulation.

Blinding during the scenario itself was not feasible due to the visible feedback device. However, participants were blinded as to study outcomes. Outcome data were collected automatically by a Laerdal manikin, and the data analyst was blinded to group allocation. Participants were asked to refrain from sharing information until data collection was complete.

Sample size calculation

The sample size was estimated using data from a previous simulation study.[11,35] A total of 32 teams were required to achieve an 80% chance of detecting, at the 5% significance level, an increase in the proportion of compressions within the target depth range (5 to 6 cm) from 41.7% in the control group to 66.5% in the experimental group, assuming a standard deviation of 24.7.

Data extraction and statistical analysis

Data were extracted from the CPREvents.xml file, obtained by unzipping the Laerdal SSX file after each simulation, and saved in a Comma-Separated Values (CSV) format before being uploaded into an SQL table *via* phpMyAdmin (version 5.0.4, https://www.phpmyadmin.net/). A PHP script automatically generated key variables, which were exported as a new CSV file for statistical analysis. There were no missing data, and data analysis was conducted blindly. All investigators had access to the anonymized, coded dataset.

Depending on the data distribution assessed visually and confirmed with the Shapiro-Wilk test as needed, the student's t-test or the Mann-Whitney U test was used. Variables were described using mean (95% CI) or median (quartiles). All statistical tests were two-sided, with statistical significance set at 5%. Data analysis was carried out using Stata V15.1 (StataCorp LLC, College Station, TX, USA).

Results

Sixty-eight participants were recruited from 8 different EMS and distributed into 34 teams (Figure 1). Their characteristics are presented in Table 1.

Primary outcome

No difference was detected in the proportion of compressions within the depth target of 5 to 6 cm with the use of a feedback device compared to no device (mean 60.5% [95% CI 50.5-70.5] versus 68.6% [95% CI 57.2-80.1]) (Figure 2). The rest of the compressions were below the target depth.

Secondary outcomes

The chest recoil was found to be more often reached in the control group than when using the feedback device (median [quartiles] 95.9% [92.2, 99.0] versus 90.2% [68.5, 95.5], p=0.024) (Figure 3). No statistical difference was detected regarding the other secondary outcomes (Table 2).

Discussion

Main considerations

No significant difference was found regarding the depth of chest compressions. This negative result warrants particular attention, especially considering that the feedback device – despite its cost – was also associated with a higher rate of inadequate chest recoil. Given that these devices are not currently associated with improved clinical outcomes,[36] their utility in real OHCA cases is questionable. This study was designed to assess the impact of adding a feedback device to an airway management strategy during OHCA, which has been shown to enhance all CPR metrics except compression depth.[11] Initially, we hypothesized that the

Table 1. Participants' characteristics.

Characteristic	Control (n=34)	Feedback device (n=34)
Gender, n (%)		
Man	16 (47.1)	22 (64.7)
Woman	17 (50.0)	12 (35.3)
Other	1 (2.9)	0 (0.0)
Profession, n (%)		
Paramedic	29 (85.3)	28 (82.4)
EMT	5 (14.7)	4 (11.8)
Nurse	0 (0.0)	2 (5.9)
Age, median (quartiles)	32 [27, 37]	35 [28, 39]
Years since diploma, median (quartiles)	5 [2, 10]	7 [2, 16]
Prehospital work experience, median (quartiles)	5 [3, 12]	11 [4, 16]
Service, n (%)		
Genève TEAM Ambulances	8 (23.5)	8 (23.5)
SK Ambulances	6 (17.7)	6 (17.7)
Ambulances des Vallées Neuchâteloises	0 (0.0)	6 (17.7)
SIS des Montagnes Neuchâteloises	4 (11.8)	2 (5.9)
ACE Genève Ambulances	2 (5.9)	2 (5.9)
SAG Secours Ambulances Genève	2 (5.9)	2 (5.9)
SPS Neuchâtel	4 (11.8)	0 (0.0)
Centre de Secours et d'Urgence de la Ville de Sion	8 (23.5)	8 (23.5)
Use of a feedback device, n (%)		
No use	15 (44.1)	8 (23.5)
Only for training	1 (2.9)	4 (11.8)
Only in the field	6 (17.7)	8 (23.5)
Both in training and in the field	12 (35.3)	14 (41.2)
If yes, using the ZOLL Real CPR Help® technology, n (%)	16 (47.1)	23 (67.6)

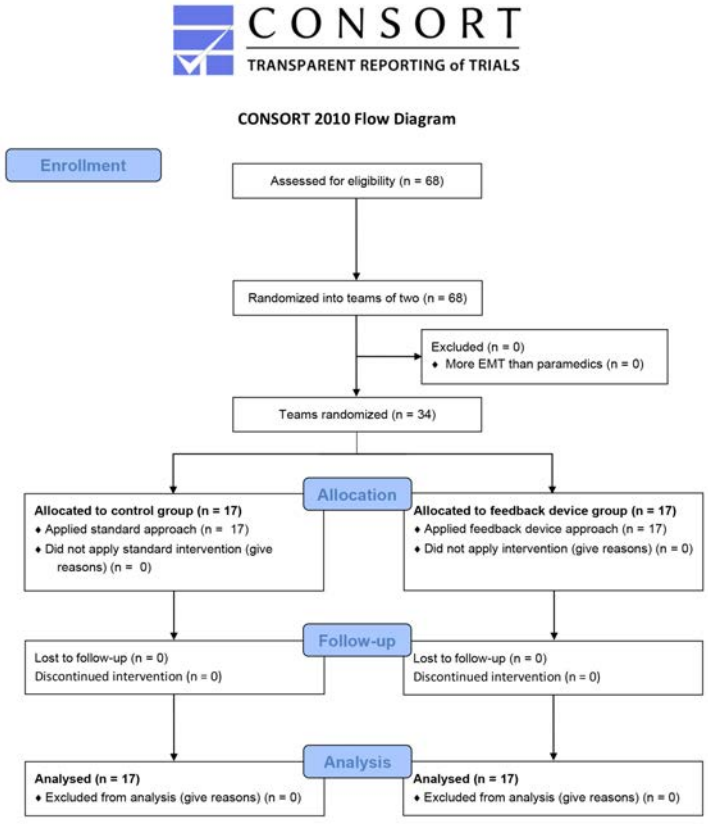

Figure 1. Study flowchart.

shallower compressions could be related to the overhead position adopted during chest compressions. However, a *post-hoc* analysis did not support this hypothesis.[37]

Two main hypotheses emerged: either the proposed approach genuinely results in shallower compressions, or the observed difference was a type I error, arising by chance due to the multiple outcomes assessed in the study. Although our sample size calculation was based on previous studies, the addition of the feedback device did not lead to any significant difference compared to the control group. Both groups achieved a proportion of compressions with correct depth, consistent with the control group from an earlier study.[11] Additionally, they mirror findings from a field study,[38] and represent an improvement over the concerning result from the previous study.[11] This suggests that the initial finding might have been a type I error. When comparing these results to those of the experimental group in the earlier trial, the findings, particularly CCF, were consistent, showing very similar trends. These results, in combination with enhanced ventilation parameters, align with the optimal targeted CCF to improve survival.[39] This reinforces our confidence in supporting direct insertion of an i-gel® without prior BVM ventilations. A registry-based study comparing Basic Life Support (BLS) teams to Advanced Life Support (ALS) teams in OHCA management also provides relevant context. Significant differences were observed: BLS teams used more SGA devices, performed more manual chest compressions, and administered adrenaline less frequently. In contrast, ALS teams performed more intubations, employed automated chest compressions, and administered adrenaline more often. Notably, survival rates were lower in the ALS group.[40] Additionally, during simulated adult OHCA, ventilation practices frequently failed to meet guideline-based targets, even when performed by well-trained EMS providers.[41] Clinical data shows that few patients received the recommended ventilation rate of 8-10 breaths per minute,[42] underscoring the critical need for tools that can support more effective ventilation.

Technical issues

The concordance between the feedback device and the SimMan 3G manikin warrants further consideration. Notably, the correlation between these tools was not evaluated, leaving the possibility of systematic bias in either data collection or the feedback provided to participants. Furthermore, the same accelerometer was used throughout the study, despite being designed for single use. While

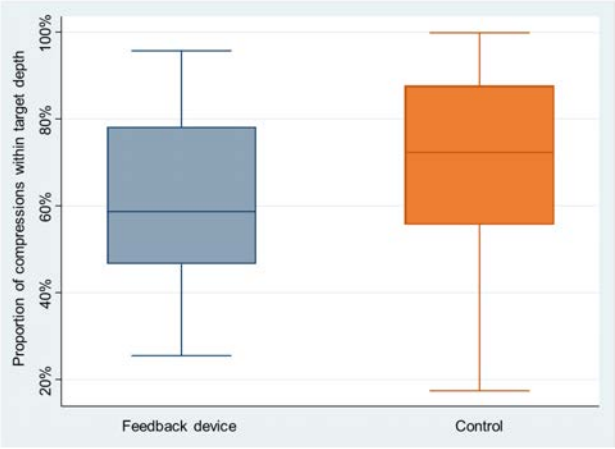

Figure 2. Proportion of compression within depth target by group.

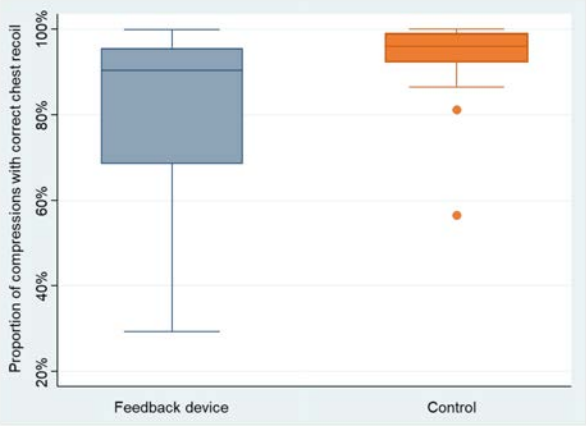

Figure 3. Proportion of compressions with correct chest recoil by group.

Table 2. Secondary outcomes.

	Control (n=17)	Feedback device (n=17)
Chest compression fraction,* %	77.0 [74.5 to 79.5]	77.8 [75.0 to 80.1]
Chest compression depth,* cm	5.1 [5.0 to 5.3]	5.1 [4.9 to 5.2]
Proportion of compression,# %		
- below rate target	0.0 (0.0, 0.6)	0.2 (0.0, 0.6)
- within rate target	85.1 (60.1, 93.7)	87.4 (79.4, 95.1)
- above rate target	12.8 (6.3, 39.4)	12.0 (4.5, 20.0)
Chest compression rate,* cpm	117 [114 to 120]	114 [112 to 116]
Time to first effective ventilation,# s	91.8 (74.7, 102.0)	84.6 (79.8, 95.3)
Time to first defibrillation,# s	36.7 (26.2, 47.5)	37.0 (35.7, 46.4)
Defibrillation attempts,# n	5 (4, 5)	5 (4, 5)
Ventilation provided,* n	46 [41 to 51]	46 [38 to 53]
Minute ventilation,# mL/min	2305 (1663, 2616)	2295 (1815, 3370)
Proportion of ventilations within target,# %	92.5 (79.3, 98.0)	98.2 (95.6, 100)

*Mean [95%CI]; #median (quartiles).

this choice was made for cost-related reasons, it is possible that initial concordance was accurate but gradually declined with repeated use, potentially affecting measurement precision. From a research perspective, assessing this concordance in future trials would be of considerable interest to ensure robust and reliable results.

Human issues

Several factors related to human behavior and training deserve discussion. First, it appears that participants may not have known how to use the feedback device correctly, likely due to insufficient training or lack of familiarity. The need for further simulation training and coaching has already been proposed.[43] In the current study, participants received only a brief explanation of the feedback device just before randomization, which may have been inadequate to ensure proper use. Moreover, even if participants were familiar with the device, its use in the study differed from typical practice. Usually, feedback is displayed directly on the defibrillator's screen. However, in this trial, due to the SimMan 3G manikin being paired with a dedicated defibrillator, feedback was displayed on a second screen located at the manikin's feet (standard ZOLL). This unconventional setup may have contributed to suboptimal utilization of the feedback device and impacted the outcomes.

Strengths and limitations

This study has some limitations that should be acknowledged. A key limitation is the lack of training provided to participants on the feedback device, which was restricted to a brief explanation before randomization. This may have influenced their ability to use the device effectively, especially given its unconventional placement at the feet of the SimMan 3G manikin instead of its usual location on the defibrillator screen. However, this limitation is somewhat mitigated by the fact that feedback devices are sometimes provided with automatic external defibrillators, and it is not uncommon for both in-hospital and pre-hospital staff to have limited exposure to these devices due to infrequent encounters with cardiac arrest scenarios. Another limitation lies in the unassessed concordance between the feedback device and the SimMan 3G, which raises concerns about potential systematic bias in both data collection and feedback delivery. Finally, while the study was based on a realistic sample size calculation, the possibility of a type II error cannot be entirely excluded, and a larger trial may be necessary to confirm these findings.

Despite these limitations, the study possesses significant strengths. The randomized controlled design ensured a high level of methodological rigor, minimizing bias and enhancing the reliability of comparisons between groups. Furthermore, the use of the high-fidelity SimMan 3G manikin provided standardized and reliable measurements of CPR quality metrics. By using a design closely aligned with the original trial,[11,35] it allowed for direct comparison of outcomes, which consistently supported the proposed airway management strategy. Specifically, the findings reinforce the approach of immediate i-gel® insertion without intermediate BVM ventilation as a viable strategy for improving CPR effectiveness.

Conclusions

This study found no significant impact of adding a feedback device to an airway management strategy in which an i-gel® is inserted immediately upon OHCA recognition, without prior BVM ventilations. Surprisingly, chest recoil was better in the absence of the feedback device. The results reinforce the validity of this approach and in line with previous research, strengthen confidence in its potential benefits. However, improved training on feedback devices and further research on tool concordance are needed to refine CPR practices and optimize patient outcomes.

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