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Clinical paper

AED applied, not recommending defibrillation – A validation study of the new variable AED in the Danish Cardiac Arrest Registry



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Abstract

Aim: This study aimed to design and implement a new variable, the automated external defibrillator (AED) variable, within the Danish Cardiac Arrest Registry. The introduction of the new variable aims to investigate and solve the challenges of reporting out-of-hospital cardiac arrests.

Methods: This validation study examined all patients with out-of-hospital cardiac arrest from 2016 to 2019. Their medical records were reviewed to establish a variable for AED. All patients with an AED applied were included, and comparative analyses were carried out. The primary outcome was 30-day survival, and the secondary outcome was the return of spontaneous circulation (ROSC) at any time.

Results: A total of 1576 cases were included; of those, 747 cases had an AED applied and received a shock, and in 829 cases, an AED was applied without delivering a shock. Most defibrillated patients were witnessed by bystanders $n = 541$, (72%). They presented a higher number of ROSC (57%) and higher 30-day survival, (35.2%) compared to patients who were not defibrillated. Of this group, only 47% patients were witnessed; 18% survived more than 30 days, $p < 0.001$. When comparing AED present with no AED present, the AED group were significantly more likely to be witnessed by bystanders and to have cardiopulmonary resuscitation by bystanders. No significant differences were found regarding the initial rhythm between the two groups. 30-day survival rate was 20% in the AED group compared to 14% in the non-AED group, yielding an OR of 1.14 (95% CI 1.20–1.66).

Conclusion: This study highlights the differences between OHCA patients receiving defibrillation and those not receiving defibrillation after AED placement. These differences emphasise the need for uniform reporting of out-of-hospital cardiac arrest. This study showed improvement in the completeness of the registration of OHCA by implementing the AED variable. However, a future effort to improve registration completeness is needed.

Keywords: Out-of-hospital cardiac arrest, AED, Utstein Style, ROSC, Survival

Background

Out-of-hospital cardiac arrest (OHCA) is associated with poor outcome and profound implications for affected patients.¹ Early identification and intervention are crucial for the return of spontaneous circulation (ROSC) and long-term survival.² Bystander cardiopulmonary resuscitation (CPR) coordinated with the use of an automated external defibrillator (AED) is essential for this purpose, as is CPR training for laypersons and AED coverage.^{3,4}

Over the past decades, national efforts have been conducted to increase survival rates after OHCA.^{2,5} Medical personnel operating

in emergency medical services (EMS) have been registering OHCA in which resuscitation has been attempted since 2001, with approximately 5,000 OHCA reported annually. Denmark has witnessed positive progress during the last 18 years of registration, with both bystander CPR and survival rates quadrupling.⁶ Data were initially registered manually, but as of 2016, they have been recorded electronically.^{7,8} Since then, the Danish Cardiac Arrest Registry (DCAR) has been a national quality database. Quality treatment and survival after cardiac arrest are internationally recognised and well-defined key indicators for overall prehospital exertions, including citizen-oriented EMS efforts.⁹

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Abbreviations

AED	automatic external defibrillator
DCAR	Danish Cardiac Arrest Registry
CPR	cardiopulmonary resuscitation
OHCA	out-of-hospital cardiac arrest

ROSC	return of spontaneous circulation
EMS	emergency medical services
ILCOR	International Liaison Committee on Resuscitation

The choice of implementing a new variable in the DCAR – namely the variable “AED” – was made considering the challenges of reporting cases in which the AED did not recommend the application of a shock after analysing cardiac rhythm. EMS personnel use contrasting nomenclatures to register this occurrence when compiling the prehospital medical record, resulting in multiple misapprehensions. Validating the new AED variable would optimise registration and be timesaving in terms of interpretation of the record – time being of the utmost importance in the event of cardiac arrest (see Fig. 1).

Prehospital health care in Denmark

Denmark is divided into five public administrative regions. Each region is responsible for its health care services, funded by the public.¹⁰ Danish EMSs are activated by a call to 1-1-2. The calls are located and forwarded to the emergency medical coordination centre where they are prioritised using the Danish Index for Emergency Care criteria.¹¹ If needed, emergency medical coordination personnel will provide the person in need with a civilian-assisted AED in the case of suspected cardiac arrest.² First responders are primarily either civilians who happen to be at the location of the incident or volunteers who have received alerts on their mobile devices upon registration. When registered in the app, one or more volunteers will be notified of the need for an AED based on their location and sent to the nearest AED device to bring it to the required location.¹²

Electronic prehospital medical record and the DCAR

The nationwide prehospital patient record stores all data concerning the prehospital patient course. One of the tabs of the prehospital medical record is entitled “cardiac arrest”. It must be explicitly com-

pleted whenever the patient has been administered CPR or fitted with an AED or a manual defibrillator. The paramedics can answer a closed-ended multiple-choice questionnaire or write a short note about the initiation of CPR, defibrillation, and ROSC. Data are then entered into electronic databases and linked to the Central Person Registry number to monitor 30-day survival. This information is associated with the DCAR, which supervises and investigates trends in the survival and treatment of OHCA in Denmark, aiming to study and improve the prognosis of OHCA victims.

This validation study sought to design and implement a new variable, AED, within the DCAR. The new variable aims to investigate and solve the challenges of reporting out-of-hospital cardiac arrests (OHCA) in the DCAR. Specifically, it addresses cases where an AED was fitted to the patient, but defibrillation was not recommended. Introducing the AED variable in the registry aims to simplify the records of OHCA, assuring better treatment and improved survival, optimising the completeness of registration by the Utstein Style for future research.

The primary outcome of this study was 30-day survival, and the secondary outcome was ROSC at any time.

Methods**Study population**

This validation study is a population-based, retrospective cohort study. The collected data source used is the DCAR. The study population was selected from all cases of OHCA occurring in Denmark from 2016 to 2019, in which either bystanders or EMS initiated resus-

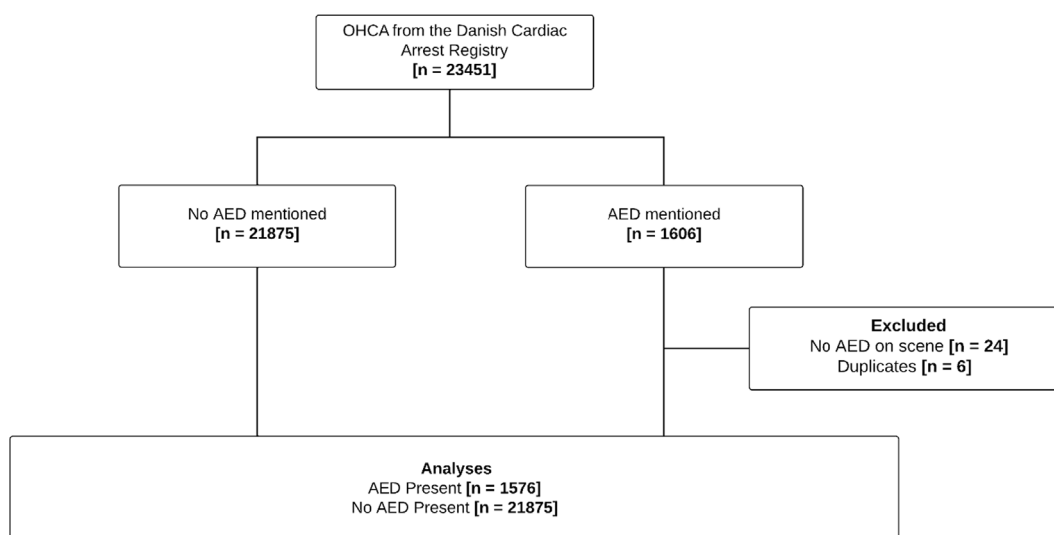


Fig. 1 – Revised STROBE chart of Inclusion. STROBE: STrengthening the Reporting of OBservational studies in Epidemiology; OHCA: out-of-hospital cardiac arrest; AED: automated external defibrillator.

citation. Of all OHCA, only the cases in which an AED was present were identified. Cases in which health professionals performed only manual defibrillation were excluded. Persons with and without a Danish Central Person Registry number -- a unique personal identification number provided to each citizen at birth and facilitates accurate linkage between all Danish national registers -- were included.¹³ Citizens without a personal identification number were accurately registered in the prehospital medical record but were not included in the further analysis from other registries.

Data

During the study period, patients with a cardiac arrest were registered in the DCAR with an AED present at the scene of the accident. Two trained medical professionals independently reviewed all the cases. Each review was initiated by confirming each patient's Central Person Registry number or, if not present, the individual record number assigned to the citizen. The validation was performed based on the prehospital medical record's free-text description. Thus, data were divided into two groups: AED present - shock delivered, hereinafter referred to as the shock group, and AED present - no shock delivered, hereinafter referred to as the non-shock group. Cases that received treatment with manual defibrillation instead of AED were excluded from the study population.

For all included cases, an assessment of whether the AED had been fitted to and delivered a shock to the patient was made. We assigned the variable AED to the case each time this specific circumstance occurred. The new AED variable contains information on the application and delivery of shock using an AED prior to the arrival of the EMS personnel. If an AED did deliver a shock, the time of defibrillation was included as well. The variable was designed considering the challenges of reporting the cases in which the AED did not recommend defibrillation. Evidence was gathered regarding the use of contrasting terminology to address this occurrence in the prehospital

medical record by the EMS. This disparate terminology led to misinterpretations. Thus, introducing the AED variable into prehospital journals aims to simplify the records of OHCA, hence optimising the treatment of cardiac arrest and survival rate, as well as the analysis registration of future research in OHCA.

Statistics

Data were collected and reported in accordance with the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) statement.¹⁴ All percentages excluded missing values. Comparative analyses were performed using non-parametric testing to examine the subgroups. Further, normative data were analysed using Fisher's exact test. Logistic regression analysis was performed for multivariate analysis. The independent association of 30-day survival was described using multiple logistic regression with odds ratios (OR) and corresponding 95% confidence intervals (95% CI). Statistical significance was considered at a p-value below 0.05 All statistical tests were performed using R-studio, version 4.1.3 (2022-03-10).

Results

The collected data comprising potential OHCA candidates during 2016–2019 ($n = 23,451$) were validated and analysed through a manual review of the medical records conducted by trained medical professionals. A total of 21,875 were identified as no AED present since no AED was mentioned, and 1606 cases were identified as AED present in which an AED was brought to the location of cardiac arrest. Further, 24 cases were excluded since there was no AED on the scene, leaving 1576 cases for comparative analyses. Figure 1 comprises a revised STROBE chart of inclusion. The demographic characteristics between cases in which an AED was present and delivered a shock or was present and did not deliver a shock are shown in Table 1.

Table 1 – Descriptives of AED present and Shock delivered compared to AED present and No shock delivered.

	AED present – Shock delivered ($N = 747$)	AED present No shock delivered ($N = 829$)	p-value
Sex, male	538(72.0)	504 (60.8)	<0.001
Missing	35	35	
Age, year, median (IQR)	70(60-79)	74(63-82)	<0.001
Missing	64	35	
Location			
Private	292(39.1)	534(64.4)	
Public	452(60.5)	292(35.2)	<0.001
Missing	3	3	
Response time, minutes, median, (IQR)	8(6-12)	9(5-12)	0.45
Missing	68	62	
Witnessed			
By Bystander	541(72.4)	393(47.4)	<0.001
By EMS	2(0.2)	14(1.7)	<0.001
Missing	5	2	
CPR by Bystander	741(99.2)	796(96.0)	
Missing	-	5	
Initial monitored cardiac rhythm (Shockable)	224(30.0)	47(5.7)	<0.001
Missing	13	20	
DC by EMS	105(14.1)	296(35.7)	<0.001
Missing	2	4	

Missing data are excluded from the denominator. AED, automated external defibrillator; IQR, interquartile range; CPR, cardiopulmonary resuscitation, DC, direct current; EMS, emergency medical system.

In 747 cases, an AED was present, and a shock was delivered; in 829 cases, an AED was present, but a shock was not delivered. Men were more likely to have a cardiac arrest in the shock group, $n = 538$ (72%), and the non-shock group, $n = 504$ (60.8%); $p < 0.001$. We found that the shock group had a lower median age (70 years, IQR 60–79) than the non-shock group (74 years, IQR 63–82); $p < 0.001$. Additionally, most patients from the shock group were found in public settings, $n = 425$ (60.5%) compared to $n = 292$ (35.2%); $p < 0.001$. Median response time was 8 minutes for the shock group and 9 minutes for the non-shock group, $p = 0.45$, showing no significant difference between the two groups. Further, the majority, $n = 541$ (72.4%) of patients from the shock group, were witnessed by bystanders. Vice versa, the non-shock group showed the reverse trend; only $n = 393$ (47.4%) were witnessed by bystanders, $p < 0.001$. Only $n = 2$ (0.2%) patients from the shock group were witnessed by EMS, compared to $n = 14$ (1.7%) from the non-shock group, $p < 0.001$. In both groups, patients received bystander CPR for most of the cases, respectively $n = 741$ (99.2%) and $n = 796$ (96%); $p < 0.001$. The recorded data showed a significant increase in the rate of initial shockable rhythm, observed and recorded by the EMS, for the shock group, $n = 224$ (30%), compared to patients from the non-shock group,

$n = 47$ (5.7%); $p < 0.001$. The outcomes of the OHCA are shown in Table 2. Patients from the shock group presented a greater number of ROSC at any time, $n = 423$ (56.6%), status at admission $n = 384$ (51.4%) and a significantly higher 30-day survival, $n = 263$ (35.2%) compared to the non-shock group. Respectively, $n = 177$ (21.4%) with ROSC at any time, $n = 149$ (18%) were alive at admission, and $n = 67$ (8.1%) were recorded with 30-day survival. All outcome comparisons were statistically significant, $p < 0.001$. Table 3 compares patients with OHCA and an AED present and patients with no AED present. More males were present in the AED group 66.1% vs 53.2%, $p < 0.001$. Public location of the OHCA was more frequent in the AED group 47.2% vs 20.9% in the non-AED group, $p < 0.001$. The response time was significantly longer within the AED group with a median of 9 minutes, IQR^{6–12} vs 6 minutes IQR^{5–10} in the non-AED group. In the AED group, the OHCA were more frequently witnessed by bystanders 55.5% vs 37.9% in the non-AED group. No significant differences were seen regarding initial rhythm or defibrillation by EMS personnel. ROSC at any time occurred more frequently in the AED group $n = 600$ vs $n = 5991$ in the non-AED group. Patients in the AED group had a 30-day survival rate of $n = 309$ (19.9%) vs $n = 3019$ (13.8%) in the non-AED group. Fig. 2 shows an adjusted regression analysis

Table 2 – Primary outcomes comparing AED present – shock delivered and AED present – No shock delivered.

	AED present – Shock delivered (N = 747)	AED present – No shock delivered (N = 829)	p-value
ROSC at any time	423(56.6)	177(21.4)	<0.001
Missing	4	2	
Status at admission (ROSC)	384(51.4)	149(18.0)	<0.001
Missing	12	4	
30-day survival	263(35.2)	67(8.1)	<0.001
Missing	66	40	

Missing data are excluded from the denominator. AED, automated external defibrillator; ROSC, return of spontaneous circulation.

Table 3 – Comparison of patients with OHCA with an AED present and with no AED present.

	AED Present (n = 1576)	No AED present (n = 21875)	p-value
Sex, male	1,042 (66.11)	11,631 (53.17)	< 0.001
Missing	70	757	
Age, years, median [IQR]	72 [61, 81]	73 [62, 82]	0.030
Missing	99	758	
Public location	744 (47.21)	4560 (20.85)	< 0.001
Missing	6	105	
Response time, median, [IQR]	9 ^{6,12}	6 ^{5,10}	0.01
Missing	130	1694	
Witnessed by bystander	875 (55.55)	8282 (37.86)	< 0.001
Missing	7	125	
CPR by bystander	1537 (97.53)	14,984 (68.50)	<0.001
Missing	6	61	
Initial shockable rhythm	271 (17.20)	3566 (16.30)	0.359
Missing	33	854	
Defibrillation by EMS personnel	401 (25.44)	4871 (22.27)	0.005
Missing	6	174	
ROSC at any time	600 (38.07)	5991(27.39)	< 0.001
Missing	6	123	
30-day survival	309 (19.60)	3019 (13.8)	< 0.001
Missing	106	829	

Missing data are excluded from the denominator. AED, automated external defibrillator; IQR, interquartile range; CPR, cardiopulmonary resuscitation, EMS, emergency medical service, ROSC: Return of spontaneous circulation.

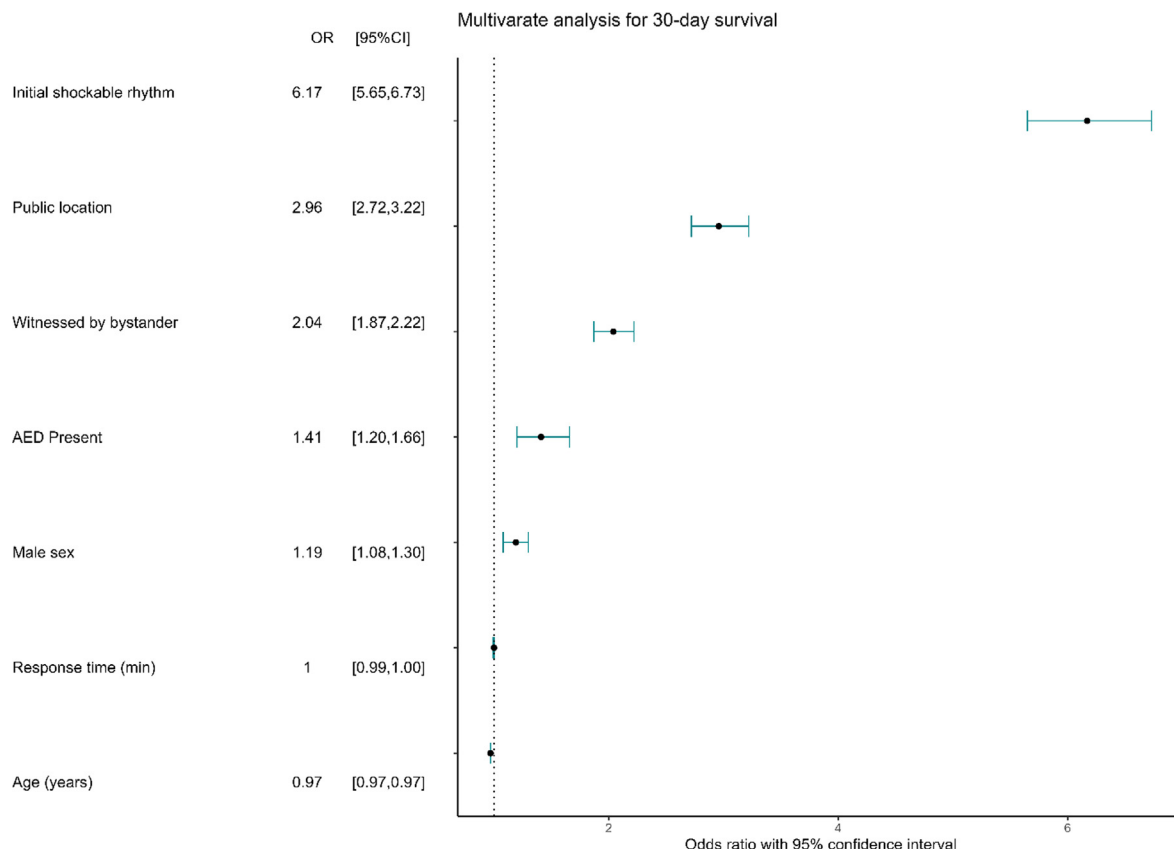


Fig. 2 – Multivariate logistic regression analysis for 30-day survival in Denmark between 2016 and 2019. OR: Odds ratio; CI: confidence interval; AED: automated external defibrillator; min: minutes.

of survival. Patients with an AED present presented with an OR for survival of 1.41 (95% CI: 1.20–1.66). Fig. 3 depicts a multivariate regression and compares the effect size of known predictors of survival between AED present and AED not present. An initial shockable rhythm was associated with high odds for survival in both groups (AED present OR: 6.51, 95%CI: 5.95–4.12; no AED present

OR: 3.16, 95% CI: 2.18 – 4.60) OHCA at a public location was also associated with increase odds for survival in both groups (AED present OR: 2.8, 95% CI: 2.56–3.06; no AED present OR: 5.90, 95% CI: 4.08–8.53). Being witnessed by bystander was also a predictor of survival in both groups (AED present OR: 5.26, 95% CI: 3.51–7.89; no AED present OR: 1.91, 95% CI: 1.75–2.09).

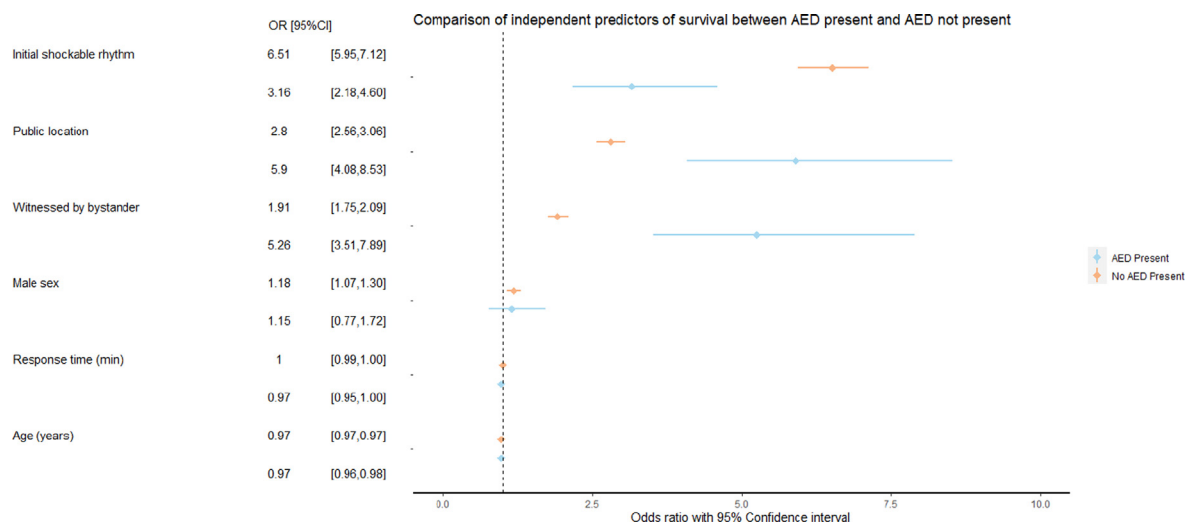


Fig. 3 – Comparison of independent predictors of survival between AED present at AED not present in Denmark between 2016 and 2019. OR: Odds ratio; CI: confidence interval; AED: automated external defibrillator; min: minutes.

Discussion

The results of this study constitute an essential step toward applying updated guidelines in reporting OHCA in Denmark, in compliance with the International Liaison Committee on Resuscitation (ILCOR) recommendations and with the Utstein style.¹⁵

The original Utstein recommendations focused on reporting cardiac arrests – of presumed cardiac cause -- witnessed by bystanders (non-EMS), with ventricular fibrillation as the first observed rhythm. This first definition was revised in 2004, aiming to reduce the complexity and update the Utstein template, now expanding the focus to include all-EMS-treated cardiac arrests regardless of the first monitored rhythm and witnessing of cardiac arrest.^{16,17}

Since this update, a considerable increase in databases and registries has increased the demand for further amendments.^{18–22} In 2013, ILCOR started a systematic review aiming, if necessary, to update the Utstein templates for cardiac arrest to compare the epidemiology and outcomes of OHCA worldwide, striving for a quality improvement in registration and thus identification of gaps in resuscitation theory.²³

Several variables and factors correlate with long-term survival after OHCA. Studies of OHCA and national databases comprising recordings of these events following the Utstein template encompass: observation of occurrence, bystander CPR, timely EMS response, initial rhythm, survival at the scene and at discharge to hospital.²⁴ The 2015 update to the Utstein style focused on additional critical elements in understanding prognostic determinants of survival in OHCA.²³ Considering this focus, there are several successful variables that other registries have implemented and that are good candidates for further improvement of the DCAR.²⁵ Concerning the importance of an AED variable, the 2015 update of the Utstein style recognises that it is essential to detect the number of cases in which bystander resuscitation is initiated and whether or not an AED was deployed and delivered a shock.²³ Different international registries have used some of these variables.^{20,26,27} However, data is scarce, and to the best of our knowledge, no prior validation studies have been carried out on the variables of interest. Thus, there is no basis for comparison regarding the evaluation of the AED variable within the registries.

Besides being reliant on the availability of devices, fitting an AED depends on the training of bystanders. A recent study found that almost 50% of the Danish population attended a basic-life support course between 2010 and 2020.²⁸ The high number of certified basic-life support individuals and general awareness in the population might contribute to the high rate of bystander-initiated CPR in the Danish setting.

The transition from paper-based registration to the now universally used electronic medical records, together with meticulous registration in the DCAR, has paved the way for continuous revision and perfecting of the registration of OHCA in Denmark.²⁹

An initial shockable cardiac rhythm is a well-known prognostic factor for favourable outcome after OHCA. The results of this study highlight differences between OHCA patients who received defibrillation and did not receive defibrillation after AED placement. The study's primary outcome was 30-day survival, and the secondary outcome was ROSC at any time. The results show how patients who were defibrillated presented a greater number of ROSC and higher 30-day survival compared to patients who were not defibrillated. The disparities between the demographic characteristics

among patients with an AED present and no AED present are expected; it is, however, interesting that no significant differences were seen for the initial rhythm. The differences in the adjusted effect size on survival support these underlying disparities within the two groups. These differences emphasise the importance of the variable AED in providing higher-quality data on OHCA. The inclusion of the AED variable, substituting the current manual revision, is yet another step in improving the registry. The results demonstrate that it could have significance in the clinical context, simplifying and maximising reporting data with clinical impact.

Limitations

Despite the clear results showing how the AED variable will improve the DCAR, there are some challenges related to both the registry and the AED variable. One of these challenges is the administrative data coverage levels on a national level. Danish data coverage using the social security number system is considered very high quality³⁰ Nevertheless, it is only partially free of different biases of administrative data. Additionally, the disease registry's extensiveness – primarily determined by its sensitivity and missing data – cannot always be ensured and does not consistently include lifestyle risk factors, such as obesity, which are particularly important in the pathogenesis of cardiac arrest.^{31,32} Moreover, cases have been registered in which no data were recorded in the prehospital medical record. These “gaps” – although minor -- present a challenge and a limitation of the database.

The number of registered AEDs has increased significantly over the last decade in Denmark and other countries. Fitting an AED is inherently dependent on the availability of the device. In a study based on data from 2008 to 2016, the authors found that almost 20% of the OHCAs were covered by AEDs at offices, almost 15% at schools, and around 12% at sports facilities, each with a coverage loss of approximately 50% as a result of limited accessibility of the AEDs in odd hours.³³ The distribution and availability of the AEDs play an essential role in the utility of AEDs, and thus the AED coverage constitutes a relevant bias within this study. Another important limitation is the role of confounders, the disparities between groups in this study might be affected by confounders and future studies should focus on addressing these.

Unfortunately, this present study does not have data on why those patients presenting with an initial shockable rhythm were not defibrillated prior to the arrival of the EMS personnel ($n = 47$). One explanation could be a do not attempt to resuscitate order; another could be the time spent fitting the AED by bystanders or that the EMS arrived just after the AED was fitted. Finally, difficulties with the use of an AED by bystanders and non-functional AEDs could account for some of the cases.³⁴

While this study validates the AED variable, it also provides the basis for future research. The latter includes the ability to provide knowledge on the use of AEDs that can be used to improve efforts targeted bystander actions such as CPR and the use of AEDs.

Conclusions

This validation study enlightened differences between patients who received a shock from an AED and those who did not, showing that the former was a proxy for higher survival rates and better out-

comes after OHCA. These differences emphasise the need to improve the completeness of the registration of OHCA. The new variable AED affects outcomes relevant to patients, as it ensures better OHCA reporting. Further, findings from this study are valuable in the planning and execution of education and campaigns targeted at healthcare professionals and laypersons. Thus, the new "AED" variable is a valid and substantial resource for future epidemiological studies. However, a future effort is needed to improve registration completeness, along with continuous improvement of the DCAR.

Ethics approval and consent to participate

As citizens of the EU, Danish citizens are subject to data protection regulated by the General Data Protection Regulation standards. In addition, these regulations are supplemented by specific Danish regulations and the Danish Executive Order of the Health Act. Ethical approval is not required for population-based retrospective registry studies in Denmark, and medical information may thus be accessed for research purposes. In this study, there was permission for access by the Danish Patient Safety Authority and storage of personal data for an extended period by the Data Protection Agency since it was recognised as necessary for the study. Therefore, all the General Data Protection Regulation requirements and other ethical considerations have been met.

Consent for publication

Not applicable.

Availability of data and materials

The data supporting this study's findings are available from the Danish Patient Safety Authority. Still, restrictions apply to the availability of these data, which were used under license for the current research and are not publicly available. Data are, however, available from the authors upon reasonable request and with permission of the Danish Patient Safety Authority.

Funding

Not applicable since no funding was received.

Authors' contributions

EC, the first author, was involved in the data curation, investigation, project administration, validation and writing original draft; SAW was involved in formal analysis methodology, investigation, software, supervision, along with editing and revising the manuscript. KBR was involved in the data curation and formal analysis of the manuscript; SNFB was involved in the data curation, editing and reviewing of the manuscript; HCC was lead of conceptualisation reviewed and edited the manuscript and was a significant contributor to writing the manuscript. All authors agreed to the study setup, data collection and analysis.

Competing Interests

The authors declare that they have no competing interests.

CRedit authorship contribution statement

Eleonora Casarini: Data curation, Methodology, Project administration, Validation, Investigation, Writing - original draft. **Signe Amalie Wolthers:** Data curation, Formal analysis, Methodology, Software, Validation. **Kristian Bundgaard Ringgren:** Supervision, Validation, Software. **Stig Nikolaj Fasmer Blomberg:** Conceptualization, Data curation, Methodology. **Helle Collatz Christensen:** Data curation, Validation, Methodology, Project administration, Supervision.

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