Avis de risque sur équipement médical

H0976 : La double défibrillation séquentielle présente un faible risque d'endommagement

DATE : 2025-01-28

PRIORITÉ : Normale

ÉQUIPEMENTS :
a) Défibrillateur automatique
b) Défibrillateur-moniteur
c) Défibrillateur-moniteur et stimulateur externe
d) Moniteur défibrillateur semi-automatique (MDSA)

FABRICANTS : Tout fabricant

MODÈLE : Tout modèle

CENTRES D'ACTIVITÉ : Service de génie biomédical, Cardiologie, Gestion matérielle, Soins intensifs, Transport ambulancier, Urgence

NOTE IMPORTANTE de Groupe Biomédical Montérégie

L'avis original a été émis par l'Institut ECRI. Les recommandations pour le Canada pourraient être différentes.

DESCRIPTION DU PROBLÈME

- Lorsqu'ils tentent de réanimer des patients difficiles à défibriller (ex : en cas de fibrillation ventriculaire récurrente ou réfractaire), le personnel clinique peut avoir recours à deux défibrillateurs pour utiliser l'une des deux approches suivantes :
  - La double défibrillation séquentielle, pour administrer des chocs en succession rapide, et;
  - La double défibrillation simultanée, pour administrer des chocs presque simultanément.
- Ces pratiques sont considérées comme non conformes à l'étiquetage pour de nombreux défibrillateurs disponibles aux États-Unis.
- Des questions ont été soulevées quant à savoir si la double défibrillation séquentielle ou simultanée endommagerait les défibrillateurs.

DISCUSSION

- L'Institut ECRI est conscient que certains établissements et organisations de services médicaux d'urgence ont commencé à pratiquer la double défibrillation séquentielle.
  - L'Institut ECRI a reçu des questions sur le risque d'endommagement des défibrillateurs et sur le type de test à effectuer après une double défibrillation séquentielle pour s'assurer du bon fonctionnement de l'appareil.
- À propos des dommages pouvant être causés aux défibrillateurs :
  - Une étude publiée en 2022, concernant un essai contrôlé aléatoire en grappe au sujet de la double défibrillation séquentielle, n'a signalé aucun incident lié à l'endommagement du

défibrillateur au cours de l'étude (voir référence [1] de la section « Documents de référence et liens utiles »).

- Une enquête publiée en 2022, menée en partie par deux auteurs de l'étude mentionnée au point précédent, a révélé que des dommages au défibrillateur ont été identifiés dans cinq cas sur environ 1 130 patients (représentant environ 0,11 à 0,22 % des chocs); dans tous les cas où un dommage est survenu, une double défibrillation simultanée a été effectuée. Aucun dommage n'a été signalé à la suite de la double défibrillation séquentielle (voir référence [2] de la section « Documents de référence et liens utiles »).
- Les fabricants des défibrillateurs aux États-Unis ont reçu quelques rapports anecdotiques de dommages résultant de la double défibrillation séquentielle ou simultanée.
  - ✓ Ils affirment qu'il est peu probable que la double défibrillation séquentielle endommage le défibrillateur, à condition que :
    - Les chocs soient délivrés de manière séquentielle, avec un délai d'au moins 10 à 100 ms (0,01 à 0,1 s) entre eux.
    - Les électrodes de défibrillation ne se touchent pas et ne se chevauchent pas.

- L'Institut ECRI estime que le risque d'endommagement du défibrillateur, lors de l'exécution de la double défibrillation séquentielle avec un espacement adéquat entre les électrodes, est suffisamment faible pour ne pas constituer un obstacle à la réalisation des actions cliniques justifiées.

POINTS DE VUE DES FABRICANTS

Philips

- Le fabricant affirme que leurs défibrillateurs sont conformes aux normes selon lesquelles les défibrillateurs doivent résister aux chocs provenant d'un second défibrillateur connecté à un patient. Par conséquent, une double défibrillation séquentielle utilisant deux défibrillateurs Philips n'annulera pas la garantie de Philips sur leurs défibrillateurs externes.
- Toutefois, la norme ne s'applique pas à la double défibrillation simultanée, dans laquelle les chocs émis par deux défibrillateurs se chevauchent pendant un certain temps. La garantie de Philips ne couvre pas les dommages résultant de cette pratique hors étiquetage.
- Pour les indications pour lesquelles l'appareil a été approuvé, référez-vous au manuel d'utilisation.

Stryker

- Les doubles défibrillations séquentielle et simultanée sont considérées comme une utilisation non conforme à l'étiquetage des défibrillateurs Stryker. Les défibrillateurs de Stryker sont conformes aux normes selon lesquelles les défibrillateurs doivent résister aux chocs provenant d'un second défibrillateur connecté à un patient. Ces normes n'incluent pas l'administration de chocs de défibrillation simultanés, séquentiels ou se chevauchant à partir de deux défibrillateurs.

  Il n'existe actuellement aucune norme de conception et/ou de sécurité reconnue pour l'utilisation de défibrillateurs externes permettant d'effectuer une double défibrillation

séquentielle. Par conséquent, Stryker ne peut garantir la fiabilité ou la fonctionnalité des appareils LIFEPAK soumis à cette utilisation hors étiquetage.

- Il existe un risque que les défibrillateurs soient endommagés par la double défibrillation séquentielle ou simultanée si une partie du courant électrique d'un défibrillateur chemine vers l'autre défibrillateur. Ce risque dépend de la synchronisation des deux chocs et de la relation spatiale entre les deux ensembles d'électrodes.
- Le fabricant recommande aux utilisateurs de vérifier le bon fonctionnement de l'appareil avant de le remettre en service. Reportez-vous à la section ‘’ Fonctionnement et entretien général ‘’ du manuel d’utilisation pour obtenir des informations sur les tests à effectuer.
- Le fabricant déclare que leur garantie ne couvre pas les dommages subis par les défibrillateurs à la suite d'une utilisation non conforme à l'étiquetage.

Zoll

- Les doubles défibrillations séquentielle et simultanée sont considérées comme une utilisation non conforme à l'étiquetage des défibrillateurs ZOLL.
- La double défibrillation séquentielle ou simultanée peut conduire à des mesures inexactes de l'impédance du patient, ce qui peut entraîner une administration d'énergie imprévisible ou des avertissements involontaires « Vérifier les électrodes » (pour une impédance élevée) ou « Court-circuit » (pour une impédance faible).

  Ce risque peut être minimisé en utilisant les configurations de coussinets antéro-latéraux et antéro-postérieurs.
- Le risque d'interférence entre deux défibrillateurs peut être évité en introduisant un délai court (>10ms) entre les chocs.

RECOMMANDATIONS ECRI

NOTE IMPORTANTE de Groupe Biomédical Montérégie

Les recommandations présentées ci-dessous sont basées sur les opinions spécifiques de l’équipe scientifique de l’Institut ECRI et concernent spécifiquement cet avis de risque.

Ces recommandations peuvent aller à l’encontre des directives locales ou pratiques spécifiques à votre établissement.

Équipe clinique (Urgence, Cardiologie, Transport ambulancier)

Si votre établissement choisit de mettre en œuvre la double défibrillation séquentielle :

- Formez le personnel à respecter scrupuleusement le protocole utilisé dans l’étude publiée en 2022 (voir référence [1] de la section « Documents de référence et liens utiles »).
  - Placez un ensemble d'électrodes de défibrillation dans la configuration antérieure-latérale et un autre ensemble dans la configuration antérieure-postérieure. Veillez à ce que les électrodes ne se chevauchent pas et ne se touchent pas, car cela pourrait endommager les électrodes, interférer avec le fonctionnement du défibrillateur ou augmenter le risque de brûlures cutanées.
  - Un seul opérateur devrait utiliser un doigt pour appuyer sur le bouton de choc des deux défibrillateurs en séquence rapide (avec une séparation d'environ 0,1 à 1 seconde).

- N’effectuez pas la double défibrillation simultanée, car cette pratique est moins prévisible. Les formes d'ondes des deux défibrillateurs peuvent interagir de manière imprévisible en fonction du moment, ce qui donne une forme d'onde qui n'a pas été testée et qui n'est pas reproductible. La double défibrillation simultanée est également plus susceptible d'endommager le défibrillateur que la double défibrillation séquentielle.
- Dans le cas improbable où l'un des défibrillateurs serait endommagé, utilisez l'autre défibrillateur pour poursuivre le traitement.
- Une fois la réanimation terminée, effectuez une inspection et une vérification opérationnelles des deux défibrillateurs avant de les remettre en service.
    - Si le manuel d’utilisation ne recommande pas spécifiquement un test opérationnel comprenant une décharge à faible énergie ou à haute énergie, envisagez de l'ajouter aux procédures standard de votre établissement à la suite de la double défibrillation séquentielle.
- Continuez à effectuer les vérifications de routine et référez-vous au manuel d’utilisation du défibrillateur pour les procédures et les listes de contrôle recommandées. Ces contrôles sont généralement recommandés tous les jours ou tous les quarts de travail. En outre, les défibrillateurs peuvent être programmés pour effectuer des autocontrôles automatiques à des moments opportuns.
    - Les autotests de l'appareil, qu'ils soient automatisés ou lancés par l'utilisateur lors des vérifications de routine, sont censés détecter les dommages ou les dysfonctionnements de l'appareil, y compris ceux résultant de l'utilisation de la double défibrillation séquentielle ou simultanée.
    - Signaler tout échec des tests au service du Génie biomédical.

Service du Génie biomédical

Si le personnel clinique de votre établissement effectue la double défibrillation séquentielle, continuez à tester les défibrillateurs comme d'habitude. Cela inclut :

- Les vérifications de routine effectuées par le personnel clinique;
- Les procédures d'inspection périodique et d’entretien préventif, conformément au protocole de l'établissement.
    - Si votre établissement est préoccupé par le risque de dommages résultant de la double défibrillation séquentielle, envisagez d'effectuer les procédures d'inspection et d’entretien préventif à des intervalles plus fréquents jusqu'à ce que vous puissiez recueillir des données concernant le taux de dommages ou de dysfonctionnements.
- Si un dommage ou un dysfonctionnement de l’appareil est identifié, en particulier s'il est associé à la double défibrillation séquentielle ou simultanée, envisagez de le signaler au fabricant et aux autorités, le cas échéant.

DOCUMENTS DE RÉFÉRENCE ET LIENS UTILES

[1] Cheskes, S., Verbeek, P.R., Drennan, I. R., McLeod, S. L., Turner, L., Pinto, R., Feldman, M., Davis, M., Vaillancourt, C., Morrison, L. J., Dorian, P. et Scales, D. C. (2022). Defibrillation Strategies for Refractory Ventricular Fibrillation. *The New England Journal of Medicine*, *387*(21), 1947-1956. (Joint à ce document).

[2] Drennan, I. R, Seidler, D. et Cheskes, S. (2022). Defibrillation Strategies for Refractory Ventricular Fibrillation. *Resuscitation Plus*, *11*, article 100287. (Joint à ce document)

ORIGINAL ARTICLE

Defibrillation Strategies for Refractory Ventricular Fibrillation

Sheldon Cheskes, M.D., P. Richard Verbeek, M.D., Ian R. Drennan, A.C.P., Ph.D., Shelley L. McLeod, Ph.D., Linda Turner, Ph.D., Ruxandra Pinto, Ph.D., Michael Feldman, M.D., Ph.D., Matthew Davis, M.D., Christian Vaillancourt, M.D., Laurie J. Morrison, M.D., Paul Dorian, M.D., and Damon C. Scales, M.D., Ph.D.

ABSTRACT

BACKGROUND

Despite advances in defibrillation technology, shock-refractory ventricular fibrillation remains common during out-of-hospital cardiac arrest. Double sequential external defibrillation (DSED; rapid sequential shocks from two defibrillators) and vector-change (VC) defibrillation (switching defibrillation pads to an anterior–posterior position) have been proposed as defibrillation strategies to improve outcomes in patients with refractory ventricular fibrillation.

METHODS

We conducted a cluster-randomized trial with crossover among six Canadian paramedic services to evaluate DSED and VC defibrillation as compared with standard defibrillation in adult patients with refractory ventricular fibrillation during out-of-hospital cardiac arrest. Patients were treated with one of these three techniques according to the strategy that was randomly assigned to the paramedic service. The primary outcome was survival to hospital discharge. Secondary outcomes included termination of ventricular fibrillation, return of spontaneous circulation, and a good neurologic outcome, defined as a modified Rankin scale score of 2 or lower (indicating no symptoms to slight disability) at hospital discharge.

RESULTS

A total of 405 patients were enrolled before the data and safety monitoring board stopped the trial because of the coronavirus disease 2019 pandemic. A total of 136 patients (33.6%) were assigned to receive standard defibrillation, 144 (35.6%) to receive VC defibrillation, and 125 (30.9%) to receive DSED. Survival to hospital discharge was more common in the DSED group than in the standard group (30.4% vs. 13.3%; relative risk, 2.21; 95% confidence interval [CI], 1.33 to 3.67) and more common in the VC group than in the standard group (21.7% vs. 13.3%; relative risk, 1.71; 95% CI, 1.01 to 2.88). DSED but not VC defibrillation was associated with a higher percentage of patients having a good neurologic outcome than standard defibrillation (relative risk, 2.21 [95% CI, 1.26 to 3.88] and 1.48 [95% CI, 0.81 to 2.71], respectively).

CONCLUSIONS

Among patients with refractory ventricular fibrillation, survival to hospital discharge occurred more frequently among those who received DSED or VC defibrillation than among those who received standard defibrillation. (Funded by the Heart and Stroke Foundation of Canada; DOSE VF ClinicalTrials.gov number, NCT04080986.)

From the Division of Emergency Medicine, Department of Family and Community Medicine (S.C., I.R.D., S.L.M.), the Division of Emergency Medicine, Department of Medicine, (P.R.V., L.J.M.), the Interdepartmental Division of Critical Care Medicine (R.P., D.C.S.), and the Department of Medicine (R.P., P.D., D.C.S.), Temerty Faculty of Medicine, University of Toronto, the Sunnybrook Centre for Prehospital Medicine (S.C., P.R.V., L.T., M.F.), the Departments of Emergency Services (I.R.D., L.J.M.) and Critical Care Medicine (R.P., D.C.S.), Sunnybrook Health Sciences Centre, the Schwartz/Reisman Emergency Medicine Institute, Sinai Health (S.L.M.), and the Division of Cardiology, Unity Health Toronto (P.D.), Toronto, the Division of Emergency Medicine, London Health Sciences Centre, Department of Medicine, University of Western Ontario, London (M.D.), and the Department of Emergency Medicine, Ottawa Hospital Research Institute, Ottawa (C.V.) — all in Canada. Dr. Cheskes can be contacted at sheldon.cheskes@sunnybrook.ca or at the Division of Emergency Medicine, Department of Family and Community Medicine, Temerty Faculty of Medicine, University of Toronto, 77 Browns Line, Ste. 100, Toronto, Ontario M8W 3S2, Canada.

Drs. Dorian and Scales contributed equally to this article.

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CME at NEJM.org

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A Quick Take is available at NEJM.org

Out-of-hospital cardiac arrest accounts for more than 350,000 unexpected deaths each year in North America; nearly 100,000 of these cardiac arrests are attributed to ventricular fibrillation or pulseless ventricular tachycardia.[1] Patients presenting with ventricular fibrillation or pulseless ventricular tachycardia have a higher survival rate than patients with other rhythms. However, despite advances in defibrillator technology, almost half these patients may remain in refractory ventricular fibrillation despite multiple defibrillation attempts.[2-5] In these patients, further defibrillation without modification of the defibrillation method is usually unsuccessful. Although antiarrhythmic medications such as amiodarone and lidocaine have been used to prevent refibrillation, neither drug has been definitively shown to improve survival to hospital discharge or neurologically intact survival.[6]

Double sequential external defibrillation (DSED), the technique of providing rapid sequential shocks from two defibrillators with defibrillation pads placed in two different planes (anterior–lateral and anterior–posterior), has been studied for decades in the electrophysiology laboratory for use in patients with refractory atrial or ventricular fibrillation.[7-10] Vector-change (VC) defibrillation, the technique of switching defibrillation pads from the anterior–lateral to the anterior–posterior position, offers the theoretical potential to defibrillate a portion of the ventricle that may not be completely defibrillated by pads in the standard anterior–lateral position. The use of DSED and VC defibrillation in settings outside the hospital has been described in case reports, observational studies, and systematic reviews.[11-16] These reports describe cases or series in which DSED was used as a last-resort therapeutic option for patients who remained in refractory ventricular fibrillation, and therefore these studies may have been confounded by resuscitation time bias or the late application of a defibrillation strategy in a subgroup of patients for whom a positive outcome was unlikely.[17] It has been suggested that early application of DSED may be associated with higher rates of termination of ventricular fibrillation and return of spontaneous circulation than standard defibrillation.[13] The objective of this trial (Double Sequential External Defibrillation for Refractory Ventricular Fibrillation [DOSE VF]) was to evaluate DSED and VC defibrillation as compared with standard defibrillation in patients who remain in refractory ventricular fibrillation during out-of-hospital cardiac arrest.

METHODS

TRIAL DESIGN

We conducted a three-group, cluster-randomized, controlled trial with crossover in six paramedic services (which include approximately 4000 paramedics in total) in Ontario, Canada (Region of Peel, Region of Halton, Toronto, County of Simcoe, Middlesex–London, and Ottawa), from March 2018 through May 2022. These paramedic services provide care to a mix of urban and rural communities with a combined population of 6.6 million and treat approximately 4100 patients with out-of-hospital cardiac arrest annually, of whom 15% present in ventricular fibrillation.[18] Prehospital medical care is provided by advanced care paramedics (with standard advanced cardiac life-support skills) and primary care paramedics (with basic life-support skills, including the ability to perform manual defibrillation). In addition to the patients enrolled in the current trial (September 10, 2019, to May 18, 2022), 152 patients who had been enrolled in a randomized, controlled pilot trial (March 8, 2018, to September 9, 2019)[19] are included in this analysis. Enrollment was paused on April 4, 2020, and resumed on September 8, 2020, to allow the paramedic services time to address concerns about paramedic safety in performing aerosol-generating procedures during the coronavirus disease 2019 (Covid-19) pandemic. The data and safety monitoring board recommended that the trial be stopped early, on May 18, 2022, because of concerns that longer response times caused by paramedic staffing shortages were interfering with the timely application of the assigned type of defibrillation.

PATIENT RECRUITMENT AND RANDOMIZATION

The trial protocol has been described previously[20] and is available (along with the statistical analysis plan) with the full text of this article at NEJM.org. The protocol was approved by the research ethics boards of Sunnybrook Health Sciences Centre, Western University, and the Ottawa Health Science Network; participants were not required to provide informed consent.

All patients who were at least 18 years of age and had an out-of-hospital cardiac arrest and re-

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fractory ventricular fibrillation of presumed cardiac causes were eligible for the trial. Refractory ventricular fibrillation was defined as an initial presenting rhythm of ventricular fibrillation or pulseless ventricular tachycardia that was still present after three consecutive rhythm analyses and standard defibrillations separated by 2-minute intervals of cardiopulmonary resuscitation (CPR). Patients with a traumatic cardiac arrest, patients with do-not-resuscitate medical directives, and patients with cardiac arrest due to drowning, hypothermia, hanging, or suspected drug overdose were excluded (Table S1 in the Supplementary Appendix, available at NEJM.org). Randomization was performed at the level of the paramedic service. Random treatment sequences were computer-generated by the coordinating center before the start of the trial. Each cluster (paramedic service) crossed over every 6 months to one of the three treatment groups (standard defibrillation, VC defibrillation, or DSED). During the trial, each service had to cross over to each of the treatment groups at least once (Table S2).

TRIAL PROTOCOL AND INTERVENTION

All paramedics followed a provincial protocol consistent with American Heart Association guidelines for the treatment of patients in ventricular fibrillation.[21,22] Continuous chest compressions were performed before application of the defibrillator pads. Each rhythm analysis occurred at standard 2-minute intervals. Ventricular fibrillation was determined by manual defibrillator rhythm analysis performed by the paramedics, after which defibrillation was provided. For all patients, the first three defibrillation attempts occurred with defibrillation pads placed in the anterior–lateral position (standard defibrillation). Eligible patients who remained in ventricular fibrillation after three consecutive shocks had been delivered by paramedics or participating fire services (defibrillation shocks provided by fire services were not counted in the pilot trial) received one of three types of defibrillation according to the random assignment for the cluster: standard defibrillation, in which all subsequent defibrillation attempts occurred with the defibrillation pads continuing in the original standard anterior–lateral configuration; VC defibrillation, in which all subsequent defibrillation attempts were delivered with defibrillation pads in an anterior–posterior configuration; or DSED, in which paramedics applied

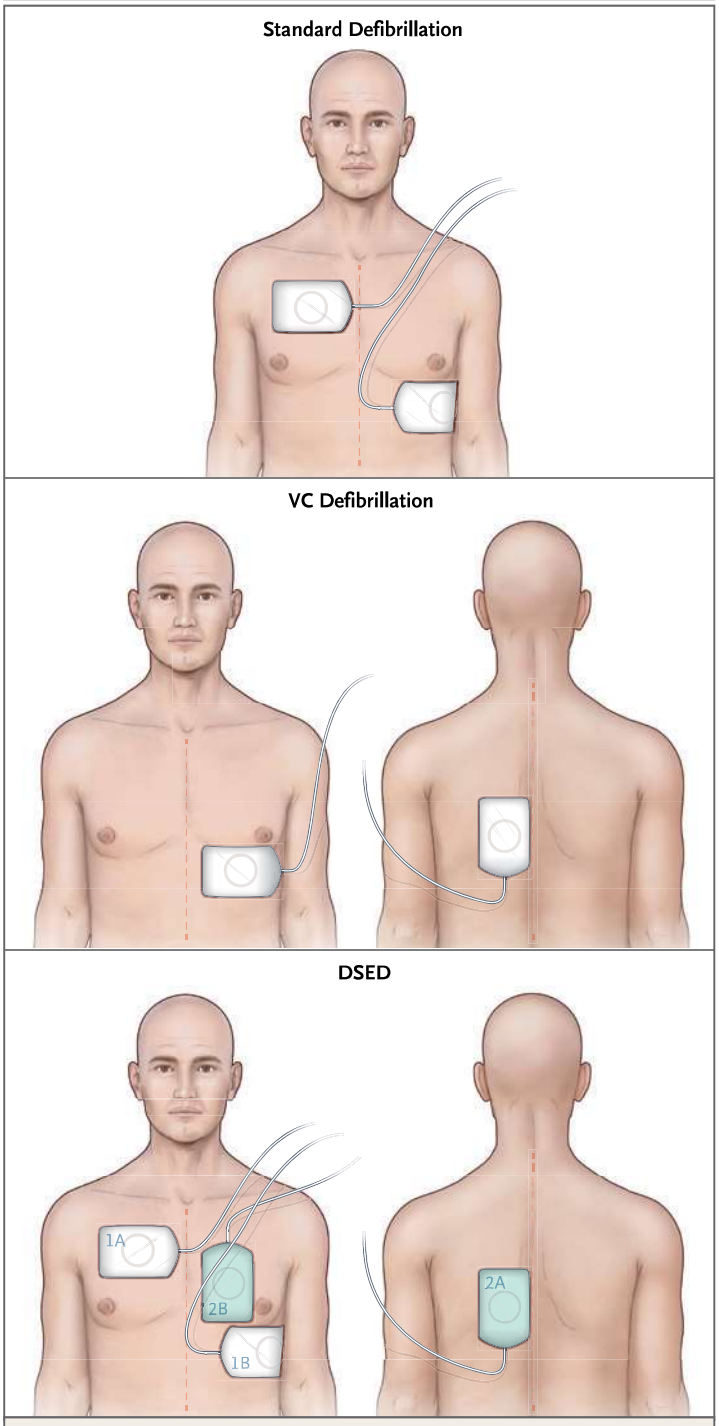


Figure 1. Pad Placement in the Three Defibrillation Strategies.

Pad placement for standard defibrillation, vector-change (VC) defibrillation, and double sequential external defibrillation (DSED) is shown. In the bottom panel, defibrillation pads 2A and 2B are those of the second defibrillator, with the pads placed in the posterior and anterior positions. For all strategies, the first three shocks occurred with pads placed in the configuration used for standard defibrillation.

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a second set of defibrillation pads (provided by a second defibrillator) in the anterior–posterior position (Fig. 1) and all subsequent defibrillation attempts were performed with the use of two near-simultaneous defibrillation shocks provided by two defibrillators. For DSED, to avoid possible defibrillator damage caused by shocks applied at the same instant, a short delay (<1 second) between shocks was created by having a single paramedic depress the "shock button" on each defibrillator in rapid sequence (anterior–lateral followed by anterior–posterior).[23]

A video showing DSED and VC defibrillation is available at NEJM.org

The defibrillation pads were placed in the required configuration as soon as possible during the 2-minute cycle of CPR after the third defibrillation attempt, with minimal interruptions in CPR. The configuration of pad placement and defibrillation is shown in Videos 1 and 2.

TRIAL OUTCOMES

The primary outcome was survival to hospital discharge. Secondary outcomes included termination of ventricular fibrillation, defined as the absence of ventricular fibrillation on subsequent rhythm analysis after defibrillation and a 2-minute interval of CPR; return of spontaneous circulation, defined as any change in rhythm to an organized rhythm with a corresponding palpable pulse or blood pressure documented by paramedics; and a good neurologic outcome at hospital discharge, defined as modified Rankin scale score of 2 or lower (scores range from 0 [no symptoms] to 6 [death]) (Table S3).

STATISTICAL ANALYSIS

We estimated 30-day survival of 28.7% among patients with out-of-hospital cardiac arrest receiving 1 to 3 shocks, declining to 12.4% among those receiving 4 to 10 shocks and 4.9% among those receiving more than 10 shocks.[5] We assumed baseline survival of 12% and hypothesized that survival to hospital discharge in the DSED and VC groups would be a minimum of 8 percentage points higher than that in the standard group. On the basis of a fixed number of paramedic service clusters (six), we expected to enroll between 20 and 70 patients per cluster over the course of 1 year. We assumed an intracluster correlation of 0.010 and an interperiod correlation of 0.008 to 0.010 without correction for multiplicity.[24-26] Under these conditions, we estimated that 310 patients per group (total sample, 930 patients) would provide 80% power at an alpha level of 0.05.

In this trial, both intervention strategies (DSED and VC defibrillation) shared a common control for comparison (standard defibrillation). The trial design assumed at least two crossovers to allow the three treatment approaches to be tested in each paramedic service. This approach was chosen to maximize efficiency, allowing the evaluation of two new treatments in comparison with usual care in a single three-group, randomized, controlled trial. The primary hypothesis was that each of these strategies would be better than usual care at a P value of less than 0.05 and without correction for multiplicity, as has been recommended for exploratory trials involving multiple treatment groups.[25,26] No interim analyses of the primary outcome were performed. All the patients were included in analyses according to their randomly assigned treatment group (intention-to-treat analysis). Prespecified sensitivity analyses included an analysis according to treatment received (regardless of the randomly assigned defibrillation strategy), a per-protocol analysis (involving patients who received the randomly assigned defibrillation at any time after the third shock), and a per-protocol analysis involving patients who were treated with optimal intervention shock timing (defined as three standard shocks followed by the assigned defibrillation strategy as the fourth shock).

Outcomes are reported as adjusted relative risks with 95% confidence intervals, with standard defibrillation as the reference group.[27] For analyses of all primary and secondary outcomes, we used generalized linear models with log link and binomial distribution, with a fixed effect for paramedic service and time since starting the trial for each paramedic service used to account for clustering of patients within a paramedic service; all analyses were adjusted for age, sex, and whether bystander CPR was received.[28] If this model would not converge for an analysis, we then used modified Poisson regression (see the Supplementary Methods section in the Supplementary Appendix).[29-31] An overall test for differences in survival to hospital discharge according to randomized treatment assignment was also performed with the randomization variable in the generalized linear model.

The widths of confidence intervals have not

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been adjusted for multiplicity, and therefore the intervals should not be used to infer definitive treatment effects for secondary outcomes. No imputation was performed for missing data. A fragility index was calculated with the use of standard equations.[32] All statistical analyses were performed with SAS software, version 9.4 (SAS Institute).

RESULTS

PATIENTS

We had enrolled 405 patients before the data and safety monitoring board suggested stopping the trial: 136 (33.6%) were assigned to the standard group, 144 (35.6%) to the VC group, and 125 (30.9%) to the DSED group (Fig. 2). Most patients (355; 87.7%) received the type of defibrillation that had been randomly assigned. The mean age of patients in the trial was 63.6 years, and 84.4% were men. A description of the representativeness of the patients included in the trial is provided in Table S4. Overall, 67.9% of out-of-hospital cardiac arrests were witnessed by bystanders and 58.0% of the patients received bystander CPR (Table 1). Resuscitation characteristics (Table S5) and treatment provided are shown in Table 2. The time to first defibrillation and the characteristics of resuscitation were similar in the three groups. Paramedics practiced high-quality CPR during the trial, consistent with current guideline recommendations.[33,34] The time and number of shocks to first return of spontaneous circulation were similar in the three groups.

OUTCOMES

A total of 38 patients (30.4%) in the DSED group survived to hospital discharge, as compared with 18 patients (13.3%) in the standard group (relative risk, 2.21; 95% confidence interval [CI], 1.33 to 3.67); the corresponding number in the VC group was 31 patients (21.7%) (relative risk [vs. standard], 1.71; 95% CI, 1.01 to 2.88) (Table 3).

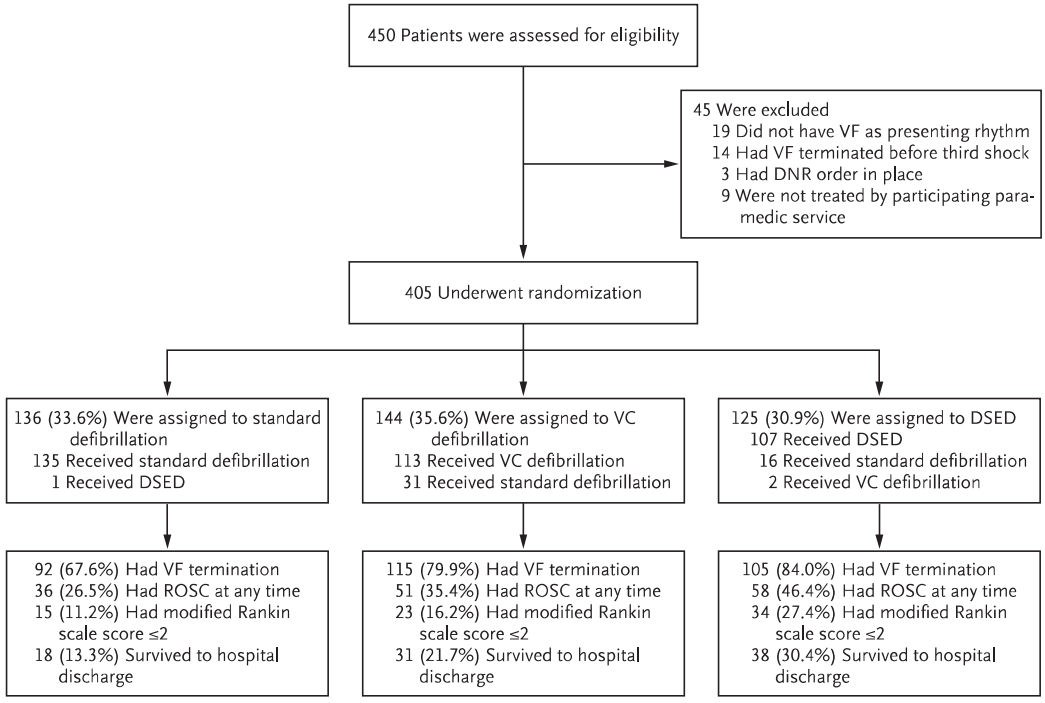


Figure 2. Trial Participants, Randomization, and Outcomes.

For survival to hospital discharge, data were missing for one patient in the standard group and one patient in the VC group. For the modified Rankin scale score, data were missing for two patients each in the standard and VC groups and for one patient in the DSED group. Modified Rankin scale scores range from 0 (no symptoms) to 6 (death). DNR denotes do not resuscitate, ROSC return of spontaneous circulation, and VF ventricular fibrillation.

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Table 1. Characteristics of the Patients.*

Characteristic	Standard Defibrillation (N=136)	VC Defibrillation (N=144)	DSED (N=125)
Age — yr	64.0±14.4	63.8±13.2	63.0±16.8
Male sex — no. (%)	109 (80.1)	127 (88.2)	106 (84.8)
Bystander-witnessed cardiac arrest — no. (%)	82 (60.3)	110 (76.4)	83 (66.4)
Bystander CPR performed — no. (%)	74 (54.4)	90 (62.5)	71 (56.8)
Public location of cardiac arrest — no. (%)	41 (30.1)	51 (35.4)	36 (28.8)
Median response time (IQR) — min†	7.4 (5.7–9.9)	7.4 (6.9–9.0)	7.8 (6.0–9.4)

* Plus–minus values are means ±SD. CPR denotes cardiopulmonary resuscitation, DSED double sequential external defibrillation, IQR interquartile range, and VC vector change.
† Response time is defined as the time from the 911 call to the arrival of paramedics at the scene. Data on first response by fire services personnel were excluded, since these data were not collected in the pilot study.

In the generalized linear model, the overall test for differences in survival to hospital discharge according to the randomized treatment assignment was significant (P=0.009 for the comparison among the three groups). The results for the termination of ventricular fibrillation, return of spontaneous circulation, survival to hospital discharge, and a modified Rankin scale score of 2 or lower are shown in Table 3. Termination of ventricular fibrillation occurred in 105 patients (84.0%) in the DSED group, as compared with 92 patients (67.6%) in the standard group (relative risk, 1.25; 95% CI, 1.09 to 1.44), and return of spontaneous circulation occurred in 58 patients (46.4%) in the DSED group, as compared with 36 (26.5%) in the standard group (relative risk, 1.72; 95% CI, 1.22 to 2.42). Survival with a good neurologic outcome occurred in 34 patients (27.4%) who received DSED and in 15 patients (11.2%) who received standard defibrillation (relative risk, 2.21; 95% CI, 1.26 to 3.88).

Among the patients who received VC defibrillation, termination of ventricular fibrillation occurred in 115 (79.9%; relative risk [vs. standard], 1.18; 95% CI, 1.03 to 1.36). The return of spontaneous circulation occurred in 51 patients in the VC group (35.4%; relative risk [vs. standard], 1.39; 95% CI, 0.97 to 1.99), and survival with a good neurologic outcome occurred in 23 (16.2%; relative risk [vs. standard], 1.48; 95% CI, 0.81 to 2.71).

The calculated fragility index for the primary outcome suggested that if nine patients in the DSED group or one patient in the VC group had not survived to hospital discharge, the results for the primary outcome would have been rendered nonsignificant. Results of the primary analysis and multiple sensitivity analyses, percentages of patients with a protocol deviation according to paramedic service, and information regarding characteristics of the receiving hospital are shown in Tables S6 through S12. The effect estimates for the primary outcome were consistent across multiple sensitivity analyses.

DISCUSSION

In this randomized, controlled trial of DSED or VC defibrillation for the treatment of refractory ventricular fibrillation during out-of-hospital cardiac arrest, survival to hospital discharge was more common among patients who received DSED or VC defibrillation than among those who received standard defibrillation. Termination of ventricular fibrillation, return of spontaneous circulation, and a good neurologic outcome at hospital discharge appeared to be more common with the DSED strategy, as did termination of ventricular fibrillation with the VC defibrillation strategy. All three groups appeared to be well matched in terms of the timing of drug administration and the mean doses of epinephrine and antiarrhythmic drugs administered, which makes an alternative therapeutic explanation for the trial findings unlikely. Although the outcomes favored DSED, the logistics of having a second defibrillator available may be a challenge in some paramedic services. Given that survival appeared higher with VC defibrillation than with standard defibrillation, the use of VC defibrillation with single-defibrillator systems may be an alternative therapeutic strategy

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Table 2. Event Characteristics.*

Characteristic	Standard Defibrillation (N=136)	VC Defibrillation (N=144)	DSED (N=125)
Median time from initial call to first shock (IQR) — min†	10.2 (8.2–13.2)	10.4 (8.8–12.6)	10.2 (8.8–11.8)
Prehospital intubation — no. (%)	52 (38.2)	72 (50.0)	53 (42.4)
Preshock pause — sec‡	6.5±7.0	6.1±6.0	6.4±7.6
Postshock pause — sec§	4.8±3.9	5.2±5.8	4.5±2.2
Compression rate per minute¶	109.8±8.0	111.1±8.4	111.7±8.7
Compression depth — cm‖	6.0±1.0	5.9±1.0	5.7±0.9
Chest compression fraction — %**	83.1±8.1	80.8±8.7	79.1±9.5
No. of standard shocks	7.4±3.0	4.2±2.1	3.9±1.4
No. of shocks to first ROSC††	5.5±1.6	5.3±1.7	5.7±1.9
Antiarrhythmic drug administered — no. (%)	110 (80.9)	106 (73.6)	92 (73.6)
Amiodarone dose — mg	403.4±75.8	392.9±76.5	378.5±75.4
Lidocaine dose — mg	185.7±73.9	175.7±60.6	162.5±83.3
Median time from arrival of EMS to first antiarrhythmic drug administration (IQR) — min‡‡	11.0 (8.0–14.0)	11.6 (9.0–16.0)	11.0 (8.0–15.5)
Epinephrine administered — no. (%)	129 (94.9)	133 (92.4)	107 (85.6)
Epinephrine dose — mg	4.2±2.2	4.2±2.0	4.0±2.1
Median time from arrival of EMS to first epinephrine dose (IQR) — min‡‡	8.7 (6.0–11.5)	9.0 (6.0–14.0)	8.8 (5.4–13.4)
Median time from arrival of EMS to first ROSC (IQR) — min‡‡	14.8 (10.6–20.0)	15.8 (12.5–19.4)	14.0 (11.0–22.0)
Median time from arrival of EMS to departure from scene (IQR) — min§§	25.0 (21.3–32.2)	27.5 (23.3–33.6)	26.5 (21.0–33.8)

* Plus–minus values are means ±SD. Patients were included in the analysis according to their randomly assigned group. ROSC denotes return of spontaneous circulation.
† Cases witnessed by emergency medical services (EMS) were excluded (11 in the standard group, 6 in the VC group, and 13 in the DSED group). Data on this variable were missing for 13 patients (5 in the standard group, 5 in the VC group, and 3 in the DSED group).
‡ Values are the mean for the first three shocks. Data on this variable were missing for 20 patients (9 in the standard group, 7 in the VC group, and 4 in the DSED group).
§ Values are the mean for the first three shocks. Data on this variable were missing for 21 patients (10 in the standard group, 7 in the VC group, and 4 in the DSED group).
¶ Data were missing for 5 patients (2 in the standard group, 2 in the VC group, and 1 in the DSED group).
‖ Data were missing for 3 patients (1 in the standard group and 2 in the VC group). Data were available only for Zoll defibrillators (289 patients).
** Data were missing for 5 patients (2 in the standard group, 2 in the VC group, and 1 in the DSED group).
†† After ROSC was achieved, the intervention was considered completed. No further shocks were counted if a repeat cardiac arrest occurred.
‡‡ Cases witnessed by EMS were excluded (11 in the standard group, 6 in the VC group, and 13 in the DSED group).
§§ Cases witnessed by EMS or with termination of resuscitation in the field were excluded (17 in the standard group, 16 in the VC group, and 14 in the DSED group).

for refractory ventricular fibrillation during out-of-hospital cardiac arrest when a second defibrillator is not available.

Our findings contrast with those of previously reported observational studies and systematic reviews that have shown no benefit of DSED or VC defibrillation as compared with standard defibrillation for patients who have had an out-of-hospital cardiac arrest.[15,35,36] However, these studies lacked a control group with standard care characterized by high-quality CPR, did not control for the timing of interventional shocks, did not describe a consistent technique for performing DSED or VC defibrillation, and did not

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Table 3. Primary and Secondary Outcomes.

Outcome	Standard Defibrillation (N=136)	VC Defibrillation (N=144)	DSED (N=125)	Adjusted Relative Risk (95% CI)*	
				DSED vs. Standard	VC vs. Standard
	number of patients/total number (percent)				
Survival to hospital discharge†	18/135 (13.3)	31/143 (21.7)	38/125 (30.4)	2.21 (1.33–3.67)	1.71 (1.01–2.88)
Termination of ventricular fibrillation	92/136 (67.6)	115/144 (79.9)	105/125 (84.0)	1.25 (1.09–1.44)	1.18 (1.03–1.36)
ROSC	36/136 (26.5)	51/144 (35.4)	58/125 (46.4)	1.72 (1.22–2.42)	1.39 (0.97–1.99)
Modified Rankin scale score ≤2†‡	15/134 (11.2)	23/142 (16.2)	34/124 (27.4)	2.21 (1.26–3.88)	1.48 (0.81–2.71)

* Adjusted relative risk values and 95% confidence intervals are derived from generalized linear models with log link and binomial distribution; analyses accounted for clustering of patients within a paramedic service with the use of a fixed effect and the time since starting the trial for all outcomes except termination of ventricular fibrillation, for which modified Poisson regression was used. All models were adjusted for age, sex, and whether bystander CPR was received. Because the statistical analysis plan did not include a provision for correcting for multiplicity when conducting tests of secondary or other outcomes, results are reported as point estimates and 95% confidence intervals. The widths of the confidence intervals have not been adjusted for multiplicity, and therefore the intervals should not be used to infer definitive treatment effects for secondary outcomes.

† Data were missing for one patient in the standard group and one patient in the VC group. In the generalized linear model, the overall test for differences in survival to hospital discharge according to the randomized treatment assignment was significant (P=0.009 for the comparison among the three groups).

‡ Data were missing for one survivor from each group. Modified Rankin scale scores range from 0 (no symptoms) to 6 (death).

measure or report the quality of CPR performed during DSED or VC defibrillation.

Our trial was implemented in urban and rural areas with 4000 paramedics trained in basic and advanced life support with the use of different defibrillators (manufactured by Zoll Medical or the Stryker Corporation), which suggests that the findings may be broadly generalizable. There was not a single reported case of defibrillator damage or malfunction when DSED was performed. Our trial design involved a common control group for the evaluation of DSED and VC defibrillation for refractory ventricular fibrillation and was meant to provide insight into whether increasing total energy or changing the defibrillation vector would offer greater benefit than standard defibrillation.[7-9,37] Our results suggest that although changing the vector of defibrillation (which changes the distribution of voltage gradients during the shock) may have a role in terminating ventricular fibrillation when previous standard defibrillation has been unsuccessful, it is possible that increasing defibrillation energy with the use of DSED also plays a role. Ideker et al. showed that when defibrillation fails to terminate ventricular fibrillation, fibrillation resumes in the region of lowest voltage and current gradient in the myocardium.[38] The anatomical location of the left ventricle, a posterior structure, is the region of the heart that is farthest from the direct line between the standard anterolateral electrode pads. VC defibrillation may result in a higher voltage gradient in the posterior part of the left ventricle, where fibrillation is most likely to restart or fail to terminate after defibrillation with standard anterior–lateral pad positions. With DSED, there is the additional influence of increased energy delivered by the second shock. Immediately after unsuccessful defibrillation of the first shock, the instantaneous wave fronts are not the same as they were during ventricular fibrillation and may be more vulnerable to successful defibrillation during the second shock than they would have been if the first "conditioning shock" had not occurred.

Our trial had several strengths, including the cluster-randomized trial design with crossover, which decreased the potential for treatment contamination among the intervention groups, as well as the near-complete outcome ascertainment, continuous performance of high-quality CPR, and the inclusion of outcomes important to patients, including survival to hospital discharge and good neurologic outcome at hospital discharge. In addition, although the treating paramedics had to be aware of the assigned defibrillation strategy,

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those assessing survival and neurologic outcomes were not aware of the treatment assignments.

This trial also has limitations. The Covid-19 pandemic provided substantial challenges to the paramedics in enrolling patients while donning full personal protective equipment and in some instances performing aerosol-generating medical procedures. The trial did not achieve the planned sample size, since it was stopped early by the data and safety monitoring board as a result of Covid-19–related operational challenges. It is possible that the treatment effect was overestimated, given the small number of events for the primary outcome.[39] The trial protocol did not specify a fixed follow-up time, and outcomes were assessed until hospital discharge. The length-of-stay distributions across the trial centers is not known. The benefit of VC defibrillation as compared with standard defibrillation should be interpreted with caution, given the fragility index of 1 for the primary outcome and a less consistent effect with regard to our secondary outcomes and sensitivity analyses. The percentage of patients who received the randomly assigned defibrillation remained consistently high (approximately 90%) throughout the trial. The inability to achieve perfect adherence to the protocol reflects the reality in which paramedics practice. The majority of patients were enrolled in an urban setting, where a second defibrillator is more often available, so the findings may not be generalizable to more remote settings. This trial was completed in the prehospital environment, and information regarding patient race and ethnic group, coexisting conditions, outpatient medication use, or in-hospital treatments was not available. Therefore, it is plausible that there could have been confounding factors that influenced patient outcomes. Finally, the trial was conducted with a high degree of medical oversight and paramedic feedback, which may not be possible in all paramedic services.

Survival to hospital discharge appeared to be higher with DSED and VC defibrillation than with standard defibrillation among patients with refractory ventricular fibrillation during out-of-hospital cardiac arrest.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

A data sharing statement provided by the authors is available with the full text of this article at NEJM.org.

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Clinical paper

A survey of the incidence of defibrillator damage during double sequential external defibrillation for refractory ventricular fibrillation

Ian R. Drennan[a,b,c,*], *Dustin Seidler*[d,e], *Sheldon Cheskes*[c,f,g]

Abstract

Background: Double Sequential External Defibrillation (DSED) is a proposed treatment strategy for patients in refractory VF (RVF) during out-of-hospital cardiac arrest (OHCA). Defibrillator damage employing DSED is a theoretical concern expressed by defibrillator manufacturers yet the incidence of damage during resuscitation remains unknown.

Objective: We sought to explore the incidence of defibrillator damage employing DSED for RVF during OHCA.

Methods: We conducted a survey of EMS agencies, authors of previous publications, EMS medical directors, base hospital medical oversight groups, and defibrillator manufacturers to assess the incidence of defibrillator damage during DSED. Our survey focused on the frequency of DSED use, number of shocks used during DSED, technique used to employ DSED (simultaneous or sequential), and the incidence of defibrillator damage during DSED. We specifically targeted groups that were known to be using DSED in clinical practice.

Results: Our survey response rate was 50% (65/129): 61% (34/56) EMS medical directors, 60% (6/10) authors, 100% (8/8) base hospitals, 33% (1/3) defibrillator manufacturers, 31% (16/52) paramedic services. In our case-based analysis the overall incidence of defibrillator damage was 0.4%. The incidence of defibrillator damage based on total number of DSED shocks was estimated between 0.11% and 0.22%. All reported cases of defibrillator damage occurred using a simultaneous defibrillation technique.

Conclusion: When DSED is employed using either a sequential or simultaneous technique the rate of defibrillator damage appears to be exceedingly low. Further high-quality evidence is required to determine the impact of DSED on patient centered outcomes, but the incidence of defibrillator damage should not limit it use. Defibrillator damage should continue to be monitored in future trials and clinical practice.

Keywords: Refractory Ventricular Fibrillation, Double sequential external Defibrillation, Defibrillator Damage, Out-of-Hospital Cardiac Arrest

Introduction

Double sequential external defibrillation (DSED) has been proposed as a potential therapeutic intervention for patients presenting in refractory ventricular fibrillation (RVF) in out-of-hospital cardiac arrest (OHCA).[1–3] The technique involves the simultaneous or rapid sequential delivery of shocks from two separate defibrillators whose pads are applied in different configurations (generally pads in the anterior-lateral position and anterior-posterior position). The use of DSED is currently not supported in either the 2020 American Heart Association Guidelines or the International Liaison Committee on Resuscitation Consensus on Science although the evidence reviewed by both bodies was considered to be of low quality.[4–5] A current ongoing randomized controlled trial, the Double Sequential External Defibrillation for Refractory Ventricular Fibrillation (DOSE VF NCT04080986) will provide the first high quality evidence as to the potential for DSED to have an impact on clinically relevant patient outcomes.[6] Regardless of the recommendations of the scientific bodies and the ongoing RCT, many agencies have implemented DSED for patients in RVF during OHCA.

One concern of using DSED is the potential to cause defibrillator damage to one of the two defibrillators used in the intervention. Gerstein et al. describe a case of defibrillator damage employing a technique similar to DSED but in a different scenario then refractory ventricular fibrillation.[7] In the case described, simultaneous shocks

* Corresponding author at: Sunnybrook Research Institute, 2075 Bayview Ave, Toronto, ON M4N 3M5, Canada.
E-mail address: Ian.Drennan@Sunnybrook.ca (I.R. Drennan).

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were delivered to perform a synchronized cardioversion in a conscious patient presenting in wide complex tachycardia employing two defibrillators by two different manufacturers (Zoll M series CCT defibrillator and Physio-Control LP 15 defibrillator). Damage was noted by the defibrillator manufacturer to be caused by a "shortage of a high-voltage component of the Therapy PCB, or printed circuit board assembly". The defibrillator manufacturer noted in their review that the defibrillator warranty provided would not cover the "off label use" of the defibrillator for techniques such as DSED. While of interest, it is clear that the application of dual shocks in the manner described is distinct from the use of DSED described in the literature for RVF in OHCA. What remains unclear is the incidence of defibrillator damage when DSED is used during RVF in current practice during OHCA. We therefore sought to explore the incidence of defibrillator damage employing the technique of DSED (either sequential or simultaneous) when employed by emergency medical services (EMS) for RVF during OHCA.

Methods

Study design

We conducted a survey of prehospital organizations and personnel with a high likelihood of DSED use within their EMS system as a result of previous research in the topic area or a known history of DSED use in the EMS agency. Individuals within each organization were invited to participate by email and surveys were completed using Google Forms®. As there was no patient or organization information collected this study met the criteria for exemption from Research Ethics Board review.

Participants

We distributed email invitations to prehospital organizations in both the United States and the province of Ontario, Canada. It was felt that these organizations represented broad coverage of EMS agencies and had a high likelihood of DSED cases within their systems based on previous reported use or publications in the area of interest.

In the United States the survey was distributed to Medical Directors who were members of the EAGLES organization.[8] The EAGLES is comprised of Medical Directors from across the United States (U. S.) covering 50 of the largest cities and approximately-one-third the U.S. population.[8,9].

In Ontario, the survey was distributed to base hospital organizations. Base hospitals are responsible for direct medical oversight and delegation to all paramedics in Ontario. There are eight base hospitals in Ontario that cover the entire province.[9]

In order to ensure that there were not cases that did not get reported to the base hospitals we also sent a secondary email to paramedic services within Ontario. There are 52 distinct paramedic services within the province. Unauthorized use of DSED is not permitted outside of the ongoing clinical trial in the province and so we felt that it is unlikely that there were additional cases of DSED that were not captured by the base hospital medical oversight groups.

Finally, we emailed authors of published literature on DSED to ask about any known defibrillator damage that they were aware of as part of their published research and the three major prehospital defibrillator manufacturers (Zoll Medical, Chelmsford, Massachusetts, Phillips Canada, Markham, Ontario, Stryker Corporation, Seattle, Washington).

Survey

The survey was a brief online questionnaire created using Google Forms®. The survey was emailed to individual participants along with a letter explaining its purpose. The survey was designed to determine the number of uses of DSED, along with any reported damage that had occurred, how the damage had been discovered, and what technique (simultaneous vs sequential) of DSED had been used. There was no prescribed method for determining the number of cases, this was left up to the individuals responding to the survey to get the most accurate number of cases. A single follow-up reminder email was sent to individuals who had not responded three weeks after the initial request. A copy of the surveys is included in Appendix A. We did not define what was meant by defibrillator damage and was left up to the discretion of the respondent as to whether there was damage that had been found. We did collect information on what the damage was and how it was identified.

Analysis

The obtained survey responses were tabulated and reported as descriptive summaries including median (interquartile range) and count (percentages). We were primarily interested in the number of cases of reported defibrillator damage. Using the results of previous studies of DSED and our ongoing randomized controlled trial (NCT04080986) we were able to estimate the total number of DSED shocks administered based on the number of cases of DSED reported by the survey respondents. This provided a better estimate of the incidence of damage on a per shock basis which is more reflective of clinical practice where most patients will require multiple shocks. From previous research the average number of DSED shocks per case was between two and four.

Results

The survey was distributed to 129 individuals and agencies. Our overall response rate was 65 (50 %). The response rates for each of the specific groups are outlined in Table 1. We found an estimated 1130 uses of DSED for OHCA from the survey respondents. From the total number of cardiac arrests, five cases (0.4 % of cases) of defibrillator damage were identified (Table 2). Two of the cases were identified as the defibrillator stopped working, the other three cases were identified on routine testing post-call. All five cases occurred using simultaneous technique where the two shock buttons are pressed together.

From the 1130 cases we were further able to estimate the total number of DSED shocks that may have occurred. Based on the responses received and the results of previous studies and our ongoing RCT we estimated an average of between 2 and 4 DSED shocks per case. This would result in a total of between 2260 and 4520 total DSED shocks, or a rate of defibrillator damage of 0.11 % to 0.22 % per shock.

Discussion

To our knowledge this is the first study exploring the risk and incidence of defibrillator damage employing DSED in practice for the treatment of cardiac arrest. The strength in our survey was the breadth of respondents including EMS medical directors, base hospitals, paramedic services, first authors of previous publications

Table 1 – Survey respondents.

	Survey Sent n	Respondents n (%)
EAGLES Medical Directors	56	34 (61)
Ontario Base Hospital Groups	8	8 (100)
Ontario Paramedic Services	52	16 (31)
Authors	10	6 (60)
Defibrillator Companies	3	1 (33)
TOTAL	129	65 (50)

Table 2 – Reported cases of defibrillator damage.

	Use of DSED	Approximate number of cases	Number of cases or reported damage
EAGLES Medical Directors	14	654	3
Ontario Base Hospital Groups	3	176	0
Ontario Paramedic Services	6	176	0
Authors	6	476	2
Defibrillator Companies	n/a	n/a	n/a
TOTAL	29	1130*	5

* Cases of Ontario Base Hospital Group and Ontario Paramedic Service are the same. Cases overlap between Authors and Ontario Base Hospital Group.

exploring DSED use in OHCA, and defibrillator manufacturers from both North America and Europe. In particular the high response rate from the EAGLES consortium of medical directors representing some of the largest EMS systems in North America suggest that the technique is not only being used for patients in RVF, but appears to be associated with an exceedingly low risk of defibrillator damage.[8] While this was true regardless of the technique (simultaneous vs sequential) employed, the risk of damage appears to be even lower with sequential defibrillation where we did not identify any cases of defibrillator damage using this technique. Finally, while the rate of defibrillator damage was exceedingly low on a per case basis the number would be even lower on a per shock basis, as most cases have multiple shocks administered, underlying the safety of DSED when employed in clinical practice. The acceptable rate of defibrillator damage from this intervention has not been established. Defining an acceptable rate of equipment damage will need to account for various factors such as any potential survival benefit associated with DSED, any threats to patient and/or provider safety, cost of damaged equipment, and any system-level impact.

There have been multiple theories to explain the potential risk of defibrillator damage during DSED. Pads applied to close to each other may direct the current from one device to the second device.[7] The use of defibrillators made by different manufacturers with differences in defibrillator biphasic waveforms (truncated exponential vs rectilinear) and energies may contribute to the potential for defibrillator damage.[10,11] The most common explanation for potential defibrillator damage that may occur during DSED is the exposure of a capacitor of the first defibrillator to high voltages generated by the second defibrillator during a specific time frame post initial defibrillator shock delivery. This exposure may be due to two defibrillators simultaneously measuring impedance in the same patient and directing energy towards the second defibrillator as opposed to the patient. Similarly, if waveforms from each defibrillator used to perform DSED occur at the exact same time, a similar result could potentially occur. Although there is a theoretical risk of defibrillator damage, the actual occurrence in real life scenarios appears to be exceedingly rare. The likely reason for this is by employing either simultaneous or rapid sequential DSED, it is nearly impossible to provide two shocks truly simultaneously (to the msec.) simply due to human reaction time.[12,13] Although the likelihood of defibrillator damage would be theoretically greater with simultaneous DSED the occurrence based on our survey results appears to be low with either technique. In the case described previously by Gerstein et al. it is more than likely that R wave synchronization by each device (which is not performed during DSED) may have led to electronic communication, in which a disturbance caused by an electromagnetic pulse from one device affects the signal in an adjacent circuit. This may have resulted in misdirection of the applied electric current from one device to the other instead of to the patient. It is important to note that the mechanisms proposed to potentially cause defibrillator damage are theoretical and not based on experimental evidence. This conclusion would seem to be supported by our survey findings.

Although the potential for defibrillator damage has been described, DSED continues to be used in clinical practice despite guidelines established by both the AHA and ILCOR. Recent research suggests that the proposed mechanism of defibrillator damage involving the exposure of one defibrillator to the voltage generated by the second defibrillator may in fact be mitigated by altering the pad position commonly used during DSED. Taylor et al. demonstrated in a pig model of DSED that peak voltage exposure was, on average, 10-fold higher for parallel than orthogonal vectors ($p < 0.0001$) of defibrillation.[14] This finding and the associated improved safety profile appear to be consistent with the findings of Cabanas et al.[15] and Cheskes et al.[6,16] who have consistently employed the orthogonal pad position during DSED and have not reported any cases of defibrillator damage during their research. The orthogonal pad position is also described by the majority of respondents in our survey perhaps further corroborating the safety profile of this pad position. Interestingly, the pad position noted in the previously published case of defibrillator damage was consistent with the parallel pad alignment associated with higher voltage exposure described by Taylor et al.

The findings of our survey must be taken in the context of the shortcomings of any survey assessing the benefit or lack thereof of any intervention. While our survey included a wide array of known and potential individuals and services employing DSED we cannot guarantee that we contacted all DSED users. Our survey response was noted to be high among EMS medical directors and base hospitals but lower among paramedic services likely related to the use of the technique only by services currently involved in the ongoing RCT. While the rate of defibrillator damage was found to be exceedingly low in our study, we cannot say with certainty that all cases of defibrillator damage were reported nor that mechanisms were established to ensure that defibrillator damage did not occur following each application of DSED. Finally, although we contacted all major defibrillator manufacturers as part of our survey, only one manufacturer responded confirming they had no reported cases of defibrillator damage employing DSED using their defibrillators.

Conclusion

When DSED is employed using either a sequential or simultaneous technique the rate of defibrillator damage appears to be exceedingly low. Further high-quality evidence is required to determine the impact of DSED on patient centered outcomes but the incidence of defibrillator damage should not appear to limit it use. The incidence of defibrillator damage should continue to be monitored in future trials and clinical practice.

Conflicts of Interest

Dr. Cheskes has received funding for educational seminars from Zoll Medical Corp. He has received research grant support from Zoll Medical Inc, Heart and Stroke Foundation of Canada and Cardiac Arrhythmia Network of Canada. He sits on the advisory board of Drone Delivery Canada. He is the PI of the ongoing Double Sequential External Defibrillation for Refractory Ventricular Fibrillation randomized controlled trial.

Dr. Drennan is the Vice-Chair of the ALS task force for the International Liaison Committee on Resuscitation (ILCOR) and member of the writing group for the 2020 AHA Guidelines for CPR and ECC.

Author Statement

All authors have met criteria for authorship and have made substantial contributions to the development of the project and final manuscript including conception and design of the study (IRD, SC, DS), acquisition of data (IRD, DS), analysis and interpretation of data (IRD, SC), drafting the article or revising it critically for important intellectual content (IRD, SC, DS) and final approval of the submitted version (IRD, SC, DS). All authors agree to be responsible for all aspects of submitted work.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.resplu.2022.100287.

Author details

[a]Sunnybrook Research Institute, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada [b]Institute of Health Policy, Management and Evaluation, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada [c]University of Toronto, Department of Family and Community Medicine, Division of Emergency Medicine, Toronto, ON, Canada [d]Toronto Paramedic Service, Toronto, ON, Canada [e]School of Health Services Management, Ryerson University, Toronto, ON, Canada[f]Sunnybrook Centre for Prehospital Medicine, Toronto, ON, Canada[g]Li Ka Shing Knowledge Institute, St. Michaels Hospital, Toronto, ON, Canada

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