Journal of EMS Medicine

Original Research

pISSN 2671-793X eISSN 2671-7948
J EMS Med 2025;4(1):17-23
https://doi.org/10.35616/jemsm.2024.00094

Received: February 4, 2024
Revised: August 9, 2024
Accepted: August 27, 2024

Correspondence to:
Shuji Sakanashi
Department of Sport and Medical Science, Kokushikan University, 7-3-1, Nagayama, Tama, Tokyo 206-8515, Japan
E-mail: sakanashis@kokushikan.ac.jp

*Shuji Sakanashi and Koshi Nakagawa are co-first authors.

Comparison of the operation time of two fully automatic external defibrillator models: a randomized controlled trial

Shuji Sakanashi[1,*], Koshi Nakagawa[2,*], Shunsuke Saito[3], Kazuki Kozakai[3], Takashi Katsurahara[1], Shumpei Omori[3], Ryu Kimura[3], Masaya Tanaka[3], Hinata Kijima[3], Hideharu Tanaka[1,3]

[1]Department of Sport and Medical Science, Kokushikan University, Tokyo, Japan
[2]Department of Integrated Science and Engineering for Sustainable Societies, Faculty of Science and Engineering, Chuo University, Tokyo, Japan
[3]Graduate School of Emergency Medical System, Kokushikan University, Tokyo, Japan

Objective: This study aimed to compare different fully automatic external defibrillators (FAEDs) among university students and examine whether they could deliver an electroshock quickly and correctly. Furthermore, we aimed to identify potential issues that could arise when disseminating FAEDs to the public.

Methods: A randomized controlled trial was conducted among university students using two commercially available FAEDs. The primary outcome measure was the time from FAED arrival to defibrillation (seconds). We used multiple linear regression analysis to estimate the partial regression coefficient and 95% confidence interval (CI) and evaluate the association between the FAED models and outcomes.

Results: Regarding the primary outcome, the mean AED arrival-defibrillation interval for Kohden was 68.33±12.18 seconds, and for Stryker, it was 75.97±12.64 seconds. The multiple regression analysis indicated that Kohden had a significantly shorter time to defibrillation compared to Stryker (B, –8.67; 95% CI, –14.93 to –2.41).

Conclusion: The study found that the two FAEDs differed by 8.67 seconds in the time from AED arrival to defibrillation. However, the subjective workload was not significantly high, suggesting that the use of automated external defibrillators was relatively straightforward.

Keywords: Defibrillators; Out-of-hospital cardiac arrest; Resuscitation; Fully automatic external defibrillator; Basic life support

INTRODUCTION

In Japan, approximately 130,000 out-of-hospital cardiac arrests (OHCAs) occur each year. Despite improvements over time, the rate of favorable neurological outcomes for witnessed cardiogenic OHCA in 2020 was only 3.5% [1]. To improve these outcomes, it is crucial for laypersons to implement a chain of survival, particularly focusing on the timely use of automated external defibrillators (AEDs) and increasing the rate of chest compressions and AED deployment [2-5]. The implementation of bystander cardiopulmonary resuscitation has been on the rise in Japan [6]. However, even with a significant number of AEDs available, public-access defibrillation (PAD) by the public remains low at 4.2%. There is still a pressing need to boost PAD rates [1].

In recent years, fully automatic external defibrillators (FAEDs), which automatically deliver an electric shock without requiring users to press a shock button, have been developed globally and became available in Japan as of July 2021 [7]. The Ministry of Health, Labour, and Welfare has instructed companies that sell or lease FAEDs to provide comprehensive explanations about the differences between FAEDs and traditional AEDs, as well as the necessary precautions and information for their use [8]. Additionally, the installation of FAEDs has been limited to specific locations, and sales are now directed at individuals who have completed training on how to use these devices [8]. As of 2024, two medical device manufacturers have introduced different FAED models to the market. However, there has been no comparison of these models in terms of features, the time it takes to deliver an electric shock, or their usability. It is crucial to understand the characteristics of each model and to choose the appropriate one based on specific needs when planning future installations of auto-shock AEDs. Therefore, the purpose of this study was to compare various FAEDs among university students and to assess whether they could administer an electroshock both quickly and accurately. Additionally, we aimed to identify potential issues that could emerge as FAEDs become more widely available to the public.

METHODS

Study design and setting

This was a parallel, 1:1 individually randomized controlled trial utilizing a prospective randomized open-blind endpoint design [9]. We adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines [10]. The study was prospectively registered at https://www.umin.ac.jp/english (identifier UMIN 000049757). Approval for the study was granted by the Ethics Committee of Kokushikan University (No.21037). Written informed consent was obtained from all participants. The study was conducted between March 28 and April 13, 2022.

Participants

Students from Kokushikan University were eligible for inclusion in this study. The subjects were individuals who had never used an AED or received any training prior to the test, and no training was provided before the test was conducted. Additionally, we established the following exclusion criteria: (1) individuals deemed incapable of performing measurements due to physical or cognitive impairments; (2) individuals who used an AED improperly; (3) individuals with missing data; and (4) instances of AED failure.

Intervention

The measurements were conducted in a private room arranged within the university. The scenario simulated an OHCA involving an adult male. The procedure began with the study provider administering chest compressions to a cardiopulmonary resuscitation mannequin, while the participant was directed to use an AED positioned near the patient. Participants operated the AED following standard usage protocols. The measurement concluded once defibrillation was successfully performed. The use of preschooler mode was prohibited. Questionnaires were distributed at the conclusion of each measurement session. The CPR manikin employed in this study was the Little Anne from Laerdal Medical. The AEDs used were the Training Unit TRN-3150 from Nihon Kohden Corporation and the Samaritan 360P from Stryker Japan K.K (Fig. 1).

Training Unit TRN-3150 (Kohden)

Upon opening the lid of the AED, the device activated and provided usage instructions through both audio and a full-color display. The defibrillation pads were immediately accessible. The AED featured a preschooler mode that could be activated as needed. An electrical shock was administered about 20 seconds after the commencement of the electrocardiogram (ECG) analysis.

Samaritan PAD 360P (Stryker)

The AED was activated by pressing the power button, which provided instructions through both audio and illuminated illustrations. The defibrillation pad was removed from the main unit, and the AED lacked a preschooler mode. An electrical shock was administered about 20 seconds following the commencement of the ECG analysis.

Randomization

We conducted a simple randomization using Rstudio, assigning participants in equal numbers to two interventions. The randomization was carried out on site in real time by the researchers before any measurements were taken. Due to the nature of the intervention, it was not possible to blind the participants; however, the data analysts were blinded.

 https://doi.org/10.35616/jemsm.2024.00094

	Nihon Kohden Corp. Training Unit TRN-3150	Stryker Japan K.K. Samaritan PAD 360P
		
Dimensions (mm)	252 (L) × 206 (W) × 100 (H)	200 (L) × 184 (W) × 48 (H)
Weight (kg)	1.3	1.1
Language	Japanese/English	Japanese
Guidance	Full-color display and audio	Audio and light
Electrocardiogram analysis-shock (sec)	Approx. 20	Approx. 19
Preschooler mode	Yes	No

Fig. 1. Types of automated external defibrillators used.

Outcomes

The primary outcome of the study was the interval between AED arrival and defibrillation (seconds). Secondary outcomes included the time from AED arrival to AED activation (seconds), from AED activation to pad attachment (seconds), and from pad attachment to defibrillation (seconds), along with the mental workload during AED operation. The mental workload was evaluated using the NASA Task Load Index (NASA-TLX), a tool designed to assess mental workload [11]. The NASA-TLX rates each of six dimensions on a visual analog scale from 0 to 100 points: mental demand, physical demand, temporal demand, performance, effort, and frustration. Typically, the mean weighted workload (WWL) score is calculated using a weighted average with paired comparison. However, calculating the WWL score involves repeated complex responses, which can be time- consuming and burdensome for participants, and it has been suggested that participants' responses may not be stable. Therefore, in this study, the RTLX (raw-TLX) was adopted to quickly and easily assess the mental workload. This method simply averages the scores for each dimension. Previous research has shown a strong correlation between RTLX and WWL, with scores ranging from 0 to 100 ($r=0.93$ to $r=0.98$). A score closer to 0 indicates a lower burden, while a score closer to 100 indicates a higher burden.

Statistical analysis

The sample size was determined using the results from the pre-measurement, aiming for a power of 80% and an alpha of 5% to detect an effect size of 0.7 or greater, based on a comparison of means between the two groups. We estimated 43 participants per group, factoring in a 15% dropout rate. Consequently, we targeted a sample size of 50 participants per group. Continuous variables were reported as means and standard deviations, and categorical variables were reported as counts and percentages. We used multiple linear regression analysis to estimate the partial regression coefficient (B) and 95% confidence interval (CI), assessing the association between the FAED models and outcomes while adjusting for the effect of confounders. The significance level was set at 0.05 (two-tailed). The study focused on analyzing the primary outcome, while the secondary outcome was considered exploratory; therefore, no adjustments were made for multiple comparisons in terms of significance levels. All analyses were conducted using R (R Foundation for Statistical Computing, version 4.1.2).

RESULTS

Participant flow

Fig. 2 illustrates the flow of participants. Informed consent was

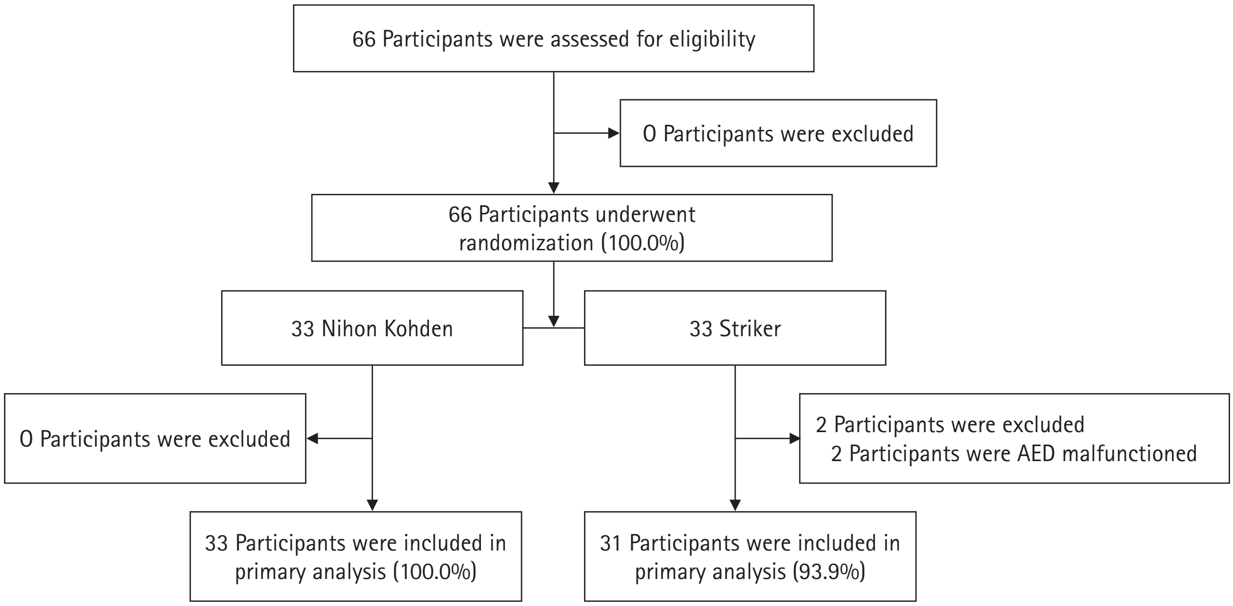

Fig. 2. Flow of the participants. AED, automated external defibrillator.

Table 1. Participants' background information according to the model of AED used

Characteristic	Overall (n = 64)	Koden (n = 33)	Stryker (n = 31)
Age (yr)	19.8 ± 0.9	19.9 ± 0.9	19.6 ± 0.8
Male sex	52 (81.3)	26 (78.8)	26 (83.9)
Department			
Physical education students	37 (57.8)	24 (72.8)	13 (41.9)
Other	27 (42.2)	9 (27.2)	18 (58.1)
School year			
1st	25 (39.1)	11 (33.3)	14 (45.2)
2nd	20 (31.3)	9 (27.3)	11 (35.5)
3rd	19 (29.7)	13 (39.4)	6 (19.4)
Previous BLS course attendance			
Yes	37 (57.8)	19 (57.6)	18 (58.1)
Unknown	2 (3.1)	1 (3.0)	1 (3.2)
Course provider (multiple choice)			
Japanese Red Cross Society	2	2	0
Driving school	28	13	15
High school or university	9	6	3
Other	3	3	0

Values are presented as mean ± standard deviation or number (%).
AED, automated external defibrillator; BLS, basic life support.

obtained from all 66 participants. They were randomly assigned to either the Kohden group or the Stryker group, with 33 participants in each group. Ultimately, 64 participants (33 Kohden and 31 Stryker) who met the eligibility criteria were included in the analysis.

Baseline data

Table 1 presents the characteristics of the participants. The mean age of the 64 participants was 19.8 years, with a standard deviation of 0.9, and 52 (81.3%) of them were men. Among these participants, 37 (57.8%) were enrolled in the Department of Sport and Physical Education, while the remaining 27 (42.2%) be-

https://doi.org/10.35616/jemsm.2024.00094

Table 2. Comparison of FAED operation time for two models

Outcome	Mean ± SD		Multiple linear regression		
	Kohden (n = 33)	Stryker (n = 31)	B[a)]	95% CI	P-value
Primary outcome					
AED arrival-defibrillation interval (sec)[b)]	68.33 ± 12.18	75.97 ± 12.64	−8.67	−14.93 to −2.41	0.007
Secondary outcome					
AED arrival-AED on (sec)[c)]	5.06 ± 3.18	6.97 ± 4.56	−2.03	−3.94 to −0.13	0.040
AED on-pads attached (sec)[d)]	40.61 ± 10.92	50.39 ± 10.73	−10.48	−16.21 to −4.75	< 0.001
Pads attached defibrillation (sec)[e)]	22.67 ± 3.10	18.48 ± 1.57	3.84	2.47 to 5.20	< 0.001
Raw-NASA-TLX (point)[f)]	42.71 ± 17.21	46.16 ± 13.69	−1.42	−9.48 to 6.63	0.730

FAED, fully automatic external defibrillator; SD, standard deviation; CI, confidence interval; AED, automated external defibrillator; NASA-TLX, NASA Task Load Index.
[a)]B were for the Koden group as compared with the Stryker group. B were adjusted for sex, department, school year, history of basic life support participation; [b)]R^2 = 0.27, adjusted R^2 = 0.18, F-test (P = 0.009); [c)]R^2 = 0.30, adjusted R^2 = 0.21, F-test (P = 0.004); [d)]R^2 = 0.28, adjusted R^2 = 0.19, F-test P = 0.008; [e)]R^2 = 0.45, adjusted R^2 = 0.39, F-test (P < 0.001); [f)]R^2 = 0.18, adjusted R^2 = 0.08, F-test (P = 0.12).

longed to various other departments. Additionally, 37 (57.8%) of the participants had undergone basic life support (BLS) training within the past 2 years. Descriptive statistics indicated no significant differences between the two groups.

Primary analysis

Table 2 presents the results of the study. In the primary outcome, the AED arrival-defibrillation interval, Kohden recorded a mean ± standard deviation of 68.33 ± 12.18 seconds, while Stryker recorded 75.97 ± 12.64 seconds. Multiple regression analysis indicated that Kohden's time to defibrillation was significantly shorter than Stryker's (B, –8.67; 95% CI, –14.93 to –2.41). In the secondary outcomes, for the AED arrival-AED on interval, Kohden's time was significantly shorter at 5.06 ± 3.18 seconds, compared to Stryker's 6.97 ± 4.56 seconds (B, –2.03; 95% CI, –3.94 to –0.13). For the AED on-pads attached interval, Kohden also showed a significantly shorter duration of 40.61 ± 10.92 seconds, versus Stryker's 50.39 ± 10.73 seconds (B, –10.48; 95% CI, –16.21 to –4.75). However, for the pads attached to defibrillation interval, Stryker was significantly shorter at 18.48 ± 1.57 seconds, compared to Kohden's 22.67 ± 3.10 seconds (B, 3.84; 95% CI, 2.47 to 5.20). In the raw-NASA-TLX analysis, no significant association was found between the models, with scores of 42.71 ± 17.21 for Stryker and 46.16 ± 13.69 for Kohden (B, –1.42; 95% CI, –9.48 to 6.63).

Concerns with FAED use

Table 3 shows which FAEDs were improperly used. In the Kohden group, there were three instances where patients were unaware of the location of the defibrillation pads. In the Stryker group, eight such cases were reported. Additionally, two patients in the Kohden group and six in the Stryker group were unclear on how to operate the AED.

Table 3. Concerns with FAED use

Improper AED use (multiple choice)	Kohden	Stryker
Did not know where the defibrillation pad	3	8
Did not understand how to turn the AED on	2	6
Attempted to apply the defibrillation pad before the AED was on	0	7
Inaccurate position of the defibrillation pad	0	2
Did not understand how to remove the defibrillation pad from the film	0	2

FAED, fully automatic external defibrillator; AED, automated external defibrillator.

DISCUSSION

This study focused on general students and compared two different FAED models available in the Japanese domestic market to determine if they could deliver electric shocks rapidly and accurately. The findings indicated a difference of 8.76 seconds in the time from the FAED's arrival to the implementation of defibrillation between the two models. However, the subjective workload was not high, suggesting that operating the FAED was relatively easy across all models.

Comparison of the operation time of the two models

This study compared the operational time for initial defibrillation using two different FAED models and found a significant time difference of 8.67 seconds. This discrepancy was primarily due to the time taken to attach the pads, with a 10.48-second difference observed between powering the device and attaching the pads. Kohden's FAED design facilitates a quicker onset and pad attachment, as the power activates upon opening the lid and the pads are immediately accessible. In contrast, Stryker's model stores the pads at the back of the main unit, necessitating additional time to locate and retrieve the pads using a handle, which delays pad attachment compared to Kohden's model. Furthermore, there were eight instances where the pad locations were unclear in the Stryker model, preventing use and raising concerns about proper AED usage due to structural issues.

A 2.03-second delay was observed between the arrival at the AED and the activation of the power button. Kohden's FAED utilizes an "open lid" design, which automatically powers on the device when the lid is opened, in contrast to Stryker's model, which requires the manual pressing of the "On/Off" button. The time taken to locate and press the power button on the AED's surface accounted for this delay. This observation is consistent with findings by Mosesso et al. [12], which suggest that an "open lid" design enables faster activation than a model with an "On/Off" button.

In addition, there were seven instances where the defibrillation pads were attached before the power button was pressed on the Stryker model. Due to the structural differences between models, the factors contributing to the time variations in defibrillation and concerns about proper usage differ. Consequently, it is essential to thoroughly elucidate the structural differences between AED models. Furthermore, early defibrillation is critical for OHCA [13], highlighting the need for standardized AED designs that enable bystanders and first responders to operate them quickly and uniformly for effective defibrillation.

Workload and concerns with FAED use

This study assessed the workload associated with using the FAED. In both models, the workload measurements were not high, suggesting that the FAED was relatively easy to use across all models. Sono et al. [14] also found that 78.4% of participants considered the FAED user-friendly, and the associated workload was not excessively high. However, this study uncovered instances of inappropriate AED use, such as not knowing where the pads were stored, failing to press the power button, and general confusion about the operations. This fundamental issue is not limited to the FAED but extends to AEDs in general, as the problem of structural variations among AEDs from different manufacturers remains unresolved.

Continued efforts are essential to educate and raise awareness among the public, especially considering the differences between specific models. It is crucial to emphasize education on the distinctions between AEDs and FAEDs, as well as the structural differences introduced by various AED manufacturers [15]. Raising awareness is necessary to address the fundamental challenges associated with AED usage and to promote effective and appropriate responses in emergency situations.

Limitations

This study has several limitations. First, it was a simulation study using training mannequins; therefore, the actual conditions at an OHCA site and the mental states of AED users may differ. Second, the mean age of the participants was approximately 20 years, and over 80% had previously undergone BLS training. Consequently, generalizing the results to older adults and laypersons without BLS training should be done with caution. Third, this study did not compare FAEDs with common AEDs, nor did it assess the relative operability of FAEDs. Additionally, there was a difference of 8.67 seconds between the arrival of the AED and the first shock administered to each model. The impact of this 8.67-second interval on the prognosis of patients with OHCA remains unclear. Nonetheless, early defibrillation is crucial for OHCA, and developing a system that enables rapid defibrillation, along with widespread educational efforts, remains a significant challenge.

Conclusion

This study compared two different FAED models among general university students to evaluate the feasibility of administering electric shocks rapidly and accurately. The findings indicated that the time from AED arrival to defibrillation varied by 8.67 seconds between the two FAEDs. Despite this variation, the subjective workload was not significantly high, suggesting that operating AEDs is relatively straightforward. A transition from conventional AEDs to FAEDs is expected in Japan. Although there are variations in operation time between the "open lid" and "On/Off" button types depending on the model, the study showed that even individuals without medical training, such as general students, can effectively use FAEDs by following audio instructions.

FUNDING

None.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

https://doi.org/10.35616/jemsm.2024.00094

AUTHORS' CONTRIBUTIONS

Conceptualization: SS (1st author), KN, HT; Formal analysis: KN, SS (3rd author); Investigation: SS (1st), SS (3rd), KK, TK, SO, MT; Methodology: KN, SS (3rd); Project administration: SS (1st), KN; Supervision: HT; Validation: KN, SO, RK, HK; Writing–original draft: SS (1st), KN; Writing–review & editing: HT, SS (1st), KN.

ACKNOWLEDGMENTS

We would like to express my heartfelt gratitude to all the participants who cooperated in this research. Additionally, I extend my thanks to Natsune Suzuki and Arata Hamashima (Department of Sport and Medical Science, Kokushikan University, Tokyo, Japan) for their invaluable assistance in the data collection process.

ORCID

Shuji Sakanashi, https://orcid.org/0000-0001-7915-8385
Koshi Nakagawa, https://orcid.org/0000-0001-8738-1261
Shunsuke Saito, https://orcid.org/0009-0002-9558-5058
Kazuki Kozakai, https://orcid.org/0009-0000-6519-7471
Takashi Katsurahara, https://orcid.org/0009-0005-9456-7933
Shumpei Omori, https://orcid.org/0009-0006-1367-3855
Ryu Kimura, https://orcid.org/0009-0003-8863-6643
Masaya Tanaka, https://orcid.org/0009-0000-1507-8378
Hinata Kijima, https://orcid.org/0009-0004-5085-1775
Hideharu Tanaka, https://orcid.org/0000-0003-4565-0026

REFERENCES

1. Fire and Disaster Management Agency. Status of EMS and fire rescue; year report of 2022 [Internet]. Fire and Disaster Management Agency; 2022 [cited 2023 Jun 29]. Available from: https://www.fdma.go.jp/publication/rescue/items/kkkg_r04_01_kyukyu.pdf
2. Hirlekar G, Jonsson M, Karlsson T, et al. Comorbidity and bystander cardiopulmonary resuscitation in out-of-hospital cardiac arrest. Heart 2020;106:1087–93.
3. Perlman JM, Wyllie J, Kattwinkel J, et al. Part 7: neonatal resuscitation: 2015 international consensus on cardiopulmonary resuscitation and emergency cardiovascular care science with treatment recommendations. Circulation 2015;132(16 Suppl 1):S204–41.
4. Monsieurs KG, Nolan JP, Bossaert LL, et al. European Resuscitation Council guidelines for resuscitation 2015. Section 1. executive summary. Resuscitation 2015;95:1–80.
5. Panchal AR, Bartos JA, Cabanas JG, et al. Part 3: adult basic and advanced life support: 2020 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation 2020;142(16_suppl_2):S366–468.
6. Sagisaka R, Nakagawa K, Kayanuma M, et al. Sustaining improvement of dispatcher-assisted cardiopulmonary resuscitation for out-of-hospital cardiac arrest patients in Japan: an observational study. Resusc Plus 2020;3:100013.
7. Nakahara S, Nagao T, Nishi R, Sakamoto T. Task-shift model in pre-hospital care and standardized nationwide data collection in Japan: improved outcomes for out-of-hospital cardiac arrest patients. JMA J 2021;4:8–16.
8. Ministry of Health, Labour and Welfare. Thoroughly provide information on precautions when using automatic external defibrillation without a shock button (auto-shock AED) [Internet]. Ministry of Health, Labour and Welfare; 2022 [cited 2022 Jun 27]. Available from: https://www.mhlw.go.jp/web/t_doc?dataId=00tc6095&dataType=1&pageNo=1
9. Ford I, Norrie J. Pragmatic trials. N Engl J Med 2016;375:454–63.
10. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. Ann Intern Med 2010;152:726–32.
11. Shigeru H, Naoki M. Japanese version of NASA Task Load Index. Jpn J Ergon 1996;32:71–9.
12. Mosesso VN, Shapiro AH, Stein K, Burkett K, Wang H. Effects of AED device features on performance by untrained laypersons. Resuscitation 2009;80:1285–9.
13. Monsieurs KG, Vogels C, Bossaert LL, Meert P, Calle PA. A study comparing the usability of fully automatic versus semi-automatic defibrillation by untrained nursing students. Resuscitation 2005;64:41–7.
14. Sono M, Sakanashi S, Nakagawa K, Takyu H, Takahashi H, Tanaka H. A comparative study of the operation time between semi-automatic and fully automatic external defibrillators for the first responder. Jpn J Reanimatol 2022;41:71–6.
15. Eames P, Larsen PD, Galletly DC. Comparison of ease of use of three automated external defibrillators by untrained lay people. Resuscitation 2003;58:25–30.