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Effect of Cognitive Aids on Adherence to Best Practice in the Treatment of Deteriorating Surgical Patients

A Randomized Clinical Trial in a Simulation Setting

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IMPORTANCE Failure to rescue causes significant morbidity and mortality in the surgical population. Human error is often the underlying cause of failure to rescue. Human error can be reduced by the use of cognitive aids.

OBJECTIVES To test the effectiveness of cognitive aids on adherence to best practice in the management of deteriorating postoperative surgical ward patients.

DESIGN, SETTING, AND PARTICIPANTS Randomized clinical trial in a simulation setting. Surgical teams consisted of 1 surgeon and 2 nurses from a surgical ward from 4 different hospitals in Amsterdam, the Netherlands. Data were analyzed between February 2, 2017, and December 18, 2018.

INTERVENTIONS The teams were randomized to manage 3 simulated deteriorating patient scenarios with or without the use of cognitive aids.

MAIN OUTCOMES AND MEASURES The primary outcome of the study was failure to adhere to best practice, expressed as the percentage of omitted critical management steps. The secondary outcome of the study was the perceived usability of the cognitive aids.

RESULTS Of the total participants, 93 were women and 51 were men. Twenty-five surgical teams performed 75 patient scenarios with cognitive aids, and 25 teams performed 75 patient scenarios without cognitive aids. Using the cognitive aids resulted in a reduction of omitted critical management steps from 33% to 10%, which is a 70% ($P < .001$) reduction. This effect remained significant (odds ratio, 0.63; 95% CI, −0.228 to −0.061; $P = .001$) in a multivariate analysis. Overall usability (scale of 0-10) of the cognitive aids was scored at a median of 8.7 (interquartile range, 8-9).

CONCLUSIONS AND RELEVANCE Failure to comply with best practice management of postoperative complications is associated with worse outcomes. In this simulation study, adherence to best practice in the management of postoperative complications improves significantly by the use of cognitive aids. Cognitive aids for deteriorating surgical patients therefore have the potential to reduce failure to rescue and improve patient outcome.

TRIAL REGISTRATION ClinicalTrials.gov identifier: NCT03812861

Invited Commentary

Supplemental content

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Human failure in the postoperative trajectory must be addressed to improve outcomes in the surgical population. Diagnostic errors and delayed treatment of complications have been shown to cause surgical adverse events more than 3 times as often as surgical errors.[1] The inability to effectively recognize and treat patients who develop complications has been termed failure to rescue.[2,3] Misapplication of the early warning score, incorrect monitoring, failure to recognize a deteriorating patient, delays in seeking senior advice, delays in diagnostics, and delays in adequate management or inadequate resuscitation have all been identified as causes for failure to rescue.[1,4-9] Human factors play a pivotal role in failure to rescue. By decreasing human failure in the complex environment of modern surgical medicine, cognitive aids have been shown to significantly reduce perioperative morbidity and mortality.[10-12] Cognitive aids target all 3 key domains associated with the timely recognition and effective management of complications in the surgical population[13]: they improve communication,[14,15] teamwork and leadership,[15-17] and the surgical safety culture[17-19] and are therefore likely to be effective in decreasing failure to rescue. More specifically, they accelerate escalation of care[20] and optimize resuscitation by reducing the amount of omitted critical treatment steps.[21]

To our knowledge, there are no cognitive aids for the management of deteriorating surgical patients. We hypothesized that cognitive aids would improve adherence to best practice in the management of deteriorating surgical patients, which was tested in a simulation setting.

Key Points

Question Would cognitive aids improve adherence to best practice in the treatment of deteriorating postoperative surgical patients?

Findings In this randomized clinical trial, the use of cognitive aids decreased the omissions of critical management steps in the management of deteriorating surgical patients by 70%. In a multivariate analysis, the use of cognitive aids was the only significant factor in reducing the omission of critical management steps.

Meaning Cognitive aids for the management of deteriorating surgical patients have the potential to reduce failure to rescue and hereby improve patient outcomes.

Methods

A randomized clinical trial was performed comparing adherence to best practice in the management of deteriorating surgical patients in the ward with and without the use of a cognitive aids. After review of the trial protocol, the medical ethics review committee of the Academic Medical Center Amsterdam declared the Act of Medical Research Involving Human Subjects (WMO) not applicable to this study (WMO W16_209#16.245), and need to comply with this legislation was therefore waived. Participants were surgeons and nurses working in surgical departments (general surgery, gynecologic surgery, and urology) in 2 tertiary teaching hospitals (Academic Medical Center Amsterdam and Vrije Universiteit Medical Center, Amsterdam, the Netherlands) and 2 general Dutch hospitals (Flevo Ziekenhuis, Almere, the Netherlands, and Tergooi Ziekenhuis, Hilversum, the Netherlands). Physicians and nurses of all levels of experience were included and were contacted by email to participate on a voluntary basis without compensation. Teams were formed on the basis of availability of the health care personnel. All participants gave written informed consent. Consolidated Standards of Reporting Trials (CONSORT) guidelines were followed to report this study. The formal trial protocols can be found in Supplement 1.

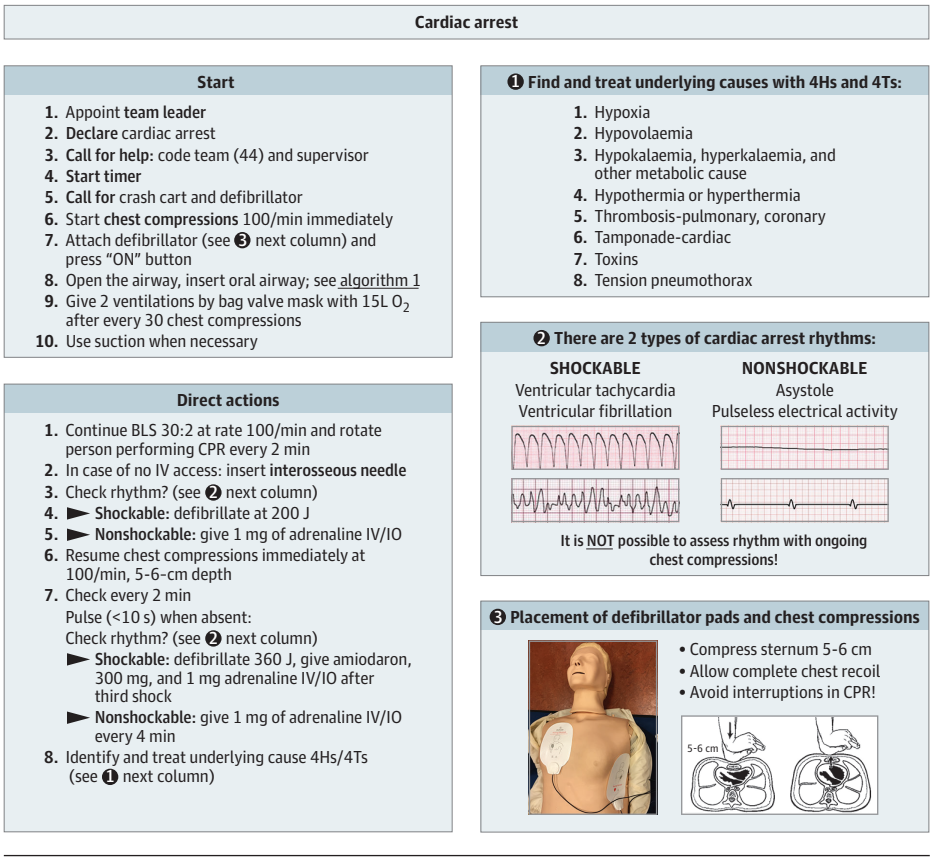
Design of the Cognitive Aids

The content of the cognitive aids for the management of deteriorating surgical patients (CAMDS) was created within an interdisciplinary expert team of anesthetic, critical care, and surgical staff of both physicians and nurses. First, conditions most associated with poor outcomes in the postoperative period were identified from the literature. Guidelines, (inter) national protocols, and relevant literature for these conditions were reviewed and incorporated in the cognitive aids.[22-27] The cognitive aids were reviewed and revised by the expert panel until full consensus was reached regarding the medical accuracy and context appropriateness of the CAMDS. To minimize following the wrong algorithm when the CAMDS were used, the subject per cognitive aids was chosen to be about a symptom or a syndrome rather than a specific diagnosis. The final CAMDS manual consists of 16 symptom-specific cognitive aids (ie, airway problem, shortness of breath, allergic reaction, chest pain, hypotension, infection, and sepsis) and 6 general algorithms (ie, ABCD approach, blood gas, and electrocardiogram analysis). A sample of the cardiac arrest algorithm is shown in **Figure 1**. The user-centered design principles that were incorporated in the cognitive aids were taken from the Dutch cognitive aids for emergencies in the operating room that were created by the authors in collaboration with the Stanford Anesthesia Cognitive Aid Group as described previously.[28-30] The cognitive aids for emergencies in the operating theater have been extensively used in both high-fidelity simulation as well as in clinical practice since 2013 in the Academic Medical Center Amsterdam. The CAMDS were tested for usability and face validity by a group of surgeons and nurses, and some minor changes were made after this process. No official pilot study was conducted prior to the start of the study; rather, it was concluded to proceed with the study on the basis of a feasibility review that was carried out after the first 6 sessions. Items that were included in the feasibility review were possibility to adhere to standardization of the scenarios, timeframe to conduct scenarios, interpretation of the patient brief, and quality of video recordings. The CAMDS are in A4 format, bundled, and have color coded tabs to facilitate navigation to the correct algorithm (eFigure in Supplement 2).

Setting and Location

The study was performed in a simulation laboratory with a standardized high-fidelity surgical ward setting. The simulation laboratory is equipped with 3 cameras and microphones.

Figure 1. Cognitive Aid: Cardiac Arrest



BLS indicates basic life support; CPR, cardiopulmonary resuscitation; IV, intravenous.

The study sessions were digitally recorded for data acquisition within Laerdal SimView (Laerdal USA). Three certified simulation operators were in charge of the simulation session and the Laerdal SimMan 3G mannequin (Laerdal USA). Ten preprogrammed standardized deteriorating surgical patient scenarios were created for the study: pneumonia with respiratory failure, pneumothorax, anaphylactic shock, postoperative bleeding, bradycardia, cardiac arrest caused by ventricular fibrillation, cardiac arrest caused by asystole, myocardial infarction, sepsis, and loss of consciousness.

All participants were novices in the use of cognitive aids. First, a standardized video introduction was given about the aim of the study and the use of cognitive aids. Subsequently, participants underwent a familiarization with the cognitive aids, the simulation laboratory in ward setting, the SimMan 3G mannequin, materials that could be used during the session (eg, crash cart and its content, medication, oxygen masks, blood drawing materials, and intravenous fluids), and use of the telephone for requesting the resuscitation or rapid response team, radiographs, and electrocardiograms. Teams were encouraged to allocate a reader[31] (someone to read the applicable algorithm out loud) in case they would be allocated to use the cognitive aids. Familiarization ended when participants felt confident to start with study sessions. Randomization occurred after study introduction and simulation laboratory familiarization to rule out biased teaching during the introduction and familiarization because both staff and participants were not aware of group allocation at this time. Teams were randomized to the intervention or control group and to 3 of 10 scenarios by opening a consecutively numbered (1-50) sealed opaque envelope that contained a computer-generated allocation code for each of the 50 teams. An independent physician had put the codes into envelopes prior to the start of the study. Every team was allocated to a cardiac arrest scenario (either a shockable or nonshockable rhythm), because this was considered a crucial clinical event to validate the CAMDS for, and 2 additional (of the remaining 8) scenarios.

When a team was randomized to the CAMDS group, the cognitive aids were left in the simulation laboratory in a dedicated place next to the hypothetical patient's bed. When the team was randomized to perform the session without the CAMDS, the cognitive aids were removed from the simulation laboratory. No comments were made about the use of other resources, such as the participant's telephones or the available computer that allowed access to the internet and local protocols. Teams were simply instructed to manage the patient as they would normally do. One of the team members (alternately) started the scenario; they were given a written brief consisting of medical history of the patient, date and type of operation the patient underwent, and clinical course up to the present. Participants were told they came for routine recording of vital signs (nurses) or a routine chat with the patient (physician). All

teams had to make the diagnosis in the scenario based on the information they had been given in the introduction and the information that they gathered at the bedside from the Laerdal manikin (vital signs displayed when monitoring attached) and additional investigations that they could order. The hypothetical patient could be asked questions when conscious (strict set of scripted answers from which simulation operator worked per scenario) and was able to cough, wheeze, or sweat. When teams called additional specialties for help, eg, the intensive care unit team or the cardiologist, the teams were given the standard answer that that specialist would come to help; they did not receive any additional information from this specialist, nor did the specialist actually come to help during the scenario. The complete simulation session took 2 hours, and teams were given around 10 minutes to complete each scenario.

For all scenarios, 15 critical management steps were predefined by the expert team based on best practice recommendations from the literature.[22-27] Team performance was measured on a total of 45 critical management steps (15 per scenario) across the 3 scenarios. Primary outcome of the study was failure to adhere to best practice, expressed as percentage of omitted critical management steps. Two independent observers scored the team's performance in adhering to all the management steps on video playback of the recorded sessions. Blinding during scoring of these sessions was not possible owing to the nature of the study. Life support feedback (depth of chest compressions, timeframes during cardiopulmonary resuscitation that no chest compressions were given, adequacy of opening the airway, rescue breaths, and joules used to defibrillate) was recorded from the Session Viewer BLS report (Laerdal USA). Steps were scored in a binary or ternary manner for the critical steps defined within a time frame. For example, in the cardiac arrest scenario, a time frame of 2 minutes was defined for calling for help and attaching the automatic external defibrillator. When a management step was performed during the scenario but not within the indicated time, 1 point was awarded rather than 2 because a patient is likely to benefit from an action even if it is performed beyond the predefined time frame. To correct for learning curve bias, scores from all 3 scenarios per group were combined to assess failure to adhere to best practice. The effect of the individual type of scenario on the primary outcome was assessed in a multivariate analysis, as described in the statistical methods.

In a postsession survey, participants scored 8 aspects of perceived usability (ease of use, logical order of described management steps, readability, whether the CAMDS provided overview, interrupted treatment, improved treatment, recommendation to use, and suitability for daily use) of the CAMDS on a 5-point Likert scale (0, strongly disagree, to 4, strongly agree). Overall usability was scored on a numerical rating scale from 0 to 10 (0, no use at all, to 10, extremely useful).

Sample Size Calculation

Sample size calculation was based on a cluster-randomized design. No previous data on the effectiveness of cognitive aids for deteriorating surgical patients in the ward were available. From data available on the use of cognitive aids in simulated crisis scenarios in the operating theater, we have seen a baseline reduction in omission of critical steps of about 75%.[21] We made a more conservative estimate that the correct application of the CAMDS would have a 50% relative reduction in the omission of critical steps. Based on this effect size and an estimated intracluster correlation coefficient within teams of 0.1 and a mean cluster size of 45, with a 2-sided α level of .05 and 80% power, 25 surgical teams per study arm (CAMDS, control), all performing 3 (of 10) scenarios, were needed. No interim analysis was planned.

Statistical Methods

Statistical analysis was performed with IBM SPSS Statistics for Windows, version 25.0 (IBM Corp). A *P* value less than .05 was considered statistically significant. Agreement between 2 observers was assessed with a Cohen κ, and distribution of data was checked using the Kolmogorov-Smirnov test. Data are presented as mean and standard deviation or median with interquartile range (IQR), depending on the distribution of the data. The Mann-Whitney *U* test was used to assess between-group differences in failure rates of adherence to best practice. In a multivariate regression model including group allocation, the effect of the experience of the participants, number of participants, and type and duration of scenario on failure rate was assessed. Descriptive statistics were used to describe the perceived usability of the CAMDS.

Results

Fifty surgical teams were randomized to CAMDS or control group in 150 simulated deteriorating surgical patient cases in sets of 3 per team. The trial ran from February 2017 to December 2018, when the 50th study session was completed. There were a total of 144 participants: 50 physicians (7 consultants, 11 senior registrars, and 32 junior registrars), of whom 42 were from general surgery, 6 from gynecology, and 2 from urology. In addition, 94 nurses participated: 82 from a general surgical ward and 14 from an oncologic gynecologic ward. Characteristics are displayed in **Table 1**. There were no dropouts. The consort flow diagram is shown in **Figure 2**.

During video review, a total of 2250 management steps (15 critical steps in each of 150 scenarios) were scored by 2 observers. Cohen κ for interrater reliability was 0.94 (97.2% agreement). In 64 management steps, there were discrepancies in scoring between the 2 reviewers. In all cases, agreement was achieved after reviewing the recorded session again.

Adherence to Best Practice

Using the CAMDS resulted in a significant decrease in the percentage of omitted critical management steps, from 33% (IQR, 22-43) to 10% (IQR, 5-16); $P < .001$ (**Figure 3**). This is a 70% reduction of missed steps (absolute risk reduction of 23%). This effect was still observed and was the only significant factor in the multivariate analysis (odds ratio [OR],

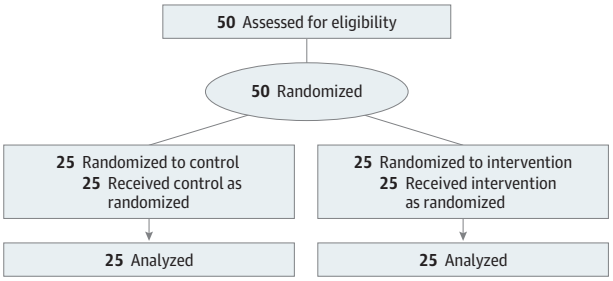
Table 1. Characteristics of Study Groups

Characteristic	No. CAMDS Group (n = 25 Teams)	Control Group (n = 25 Teams)
Participants	71	73
1 Physician, 2 nurses	21 Teams	23 Teams
1 Physician, 1 nurse	4 Teams	2 Teams
Type of scenario		
Pneumonia	9	4
Pneumothorax	9	9
Anaphylactic shock	6	7
Hemorrhage	5	6
Bradycardia	5	3
Cardiac arrest, shock	9	11
Cardiac arrest, no-shock	16	14
Myocardial infarction	2	8
Sepsis	5	5
Loss of consciousness	9	8
Clinical experience of physicians, median (IQR), y[a]	2 (1-5)	3 (2-5)
Clinical experience nurses, median (IQR), y[a]	4 (2-9)	5 (3-11)
Duration of simulation session, rate (95% CI), s	643.7 (596.3-691)	612.1 (564.8-659.3)

Abbreviations: CAMDS, cognitive aids for the management of deteriorating surgical patients; IQR, interquartile range.

[a] In current role.

Figure 2. Consort Flow Diagram



0.63; 95% CI, −0.228 to −0.061; P = .001), which included group allocation, experience of the participants, number of participants, and type and duration of scenario. Use of the CAMDS also resulted in a significant decrease in failure to adhere to best practice management for each scenario individually (eTable 2 in Supplement 2). In 8% of the sessions (6 of 75), the cognitive aids were not used despite being available in the scenario (intervention group). Per protocol analysis resulted in a decrease in the percentage of omitted critical management steps from 33% (IQR, 22-42) to 6% (IQR, 5-16; P < .001). This is an 82% reduction of missed steps (absolute risk reduction of 27%). In 1 case (0.6%), the wrong cognitive aid was followed; the cognitive aid with the sepsis algorithm was used in an actual anaphylaxis scenario.

Perceived Usability

Table 2 shows the responses to the perceived usability survey. Overall usability (0-10) of the CAMDS was scored at a median of 8.7 (IQR, 8-9). All participants rated the scenarios to be realistic (ie, resembling daily clinical work); 4% neutral (n = 6), 54% agreed (n = 78), and 42% strongly agreed (n = 60).

Discussion

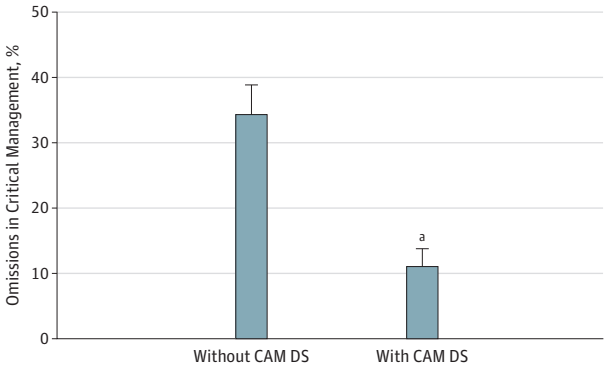
Cognitive aids, as a tool to prevent human error, reduced the omissions of critical steps in the management of deteriorating surgical patients in the ward from 33% to 10% (relative reduction of 70%). The baseline omission of 33% of critical management steps found in this study corroborates previously reported incidences between 20% to 50%.[21,32-34] A case note review in the care of surgical patients[35] also revealed a noncompliance rate in best practice of 86% in the management of postoperative complications. Failure to comply with best practice was found to be the only significant factor in the development of further complications (OR, 6.75; 95% CI, 1.11-41.00) in this study.[35] Another study[36] also showed that failure to adhere to critical management steps in postoperative care significantly predicted the occurrence of a complication, and that each additional management step missed increased the odds of a postoperative complication by 60% (OR, 1.6; 95% CI, 1.2-2.2).[36] Failure to adhere to best practice thus not only occurs in simulation sessions but in clinical practice every day, resulting in preventable morbidity and mortality. It is therefore critical to improve adherence to best practice management.

Limitations

A limitation of this study is that it was performed in a simulation setting; the effect of the use of cognitive aids for deteriorating surgical patients on clinical outcome measures is therefore yet to be established. The assessment rubric used to test the intervention was not validated prior to the study. However, this rubric is exclusively composed of 15 recommended management steps that could be scored performed or not, taken from the literature. The rationale to assess 15 management steps for all scenarios was a pragmatic decision for the purpose of the sample size calculation because 15 steps seemed the mean number of critical management steps per scenario during the development of the scoring cards. However, although the assessment tool describes the recommended treatment steps from the literature, not all steps are likely to have the same effect in the real world. Furthermore, it was not possible to blind the judges to the use of cognitive aids in this study. Although this is a potential source of bias, it is unlikely to affect the results of the study because the management steps are unambiguous to score (ie, feedback from the Laerdal manikin or administration of antibiotics; teams were awarded 0 points if they did not administer the antibiotics even if they mentioned that they were going to administer them).

Another potential limitation of the study is the relatively small number of participating consultants. Because participation was on a voluntary basis, it was more difficult

Figure 3. Failure to Adhere to Best Practice Expressed as Percentage of Omitted Critical Management Steps



[a] Performing the scenarios without cognitive aids for the management of deteriorating surgical patients resulted in a significantly higher percentage of omitted critical management steps.

Table 2. Perceived Usability (Likert Scale: 0, Strongly Disagree, to 4, Strongly Agree)

Item	Median (IQR)
Ease of use	3 (3-3.5)
Logical order management steps	3.3 (3-3.7)
Readability	3.3 (3-3.7)
Provided overview	3.3 (3-3.5)
Interrupted treatment	1 (0.7-1.3)
Improved treatment	3.3 (3-3.7)
Recommendation to use	3.6 (3.2-3.7)
Suitability for daily use	3.7 (3.3-3.8)

Abbreviation: IQR, interquartile range.

for consultants to find time to participate. This could have introduced bias by deficiency of senior input in a proportion of teams. However, in clinical practice, junior physicians are usually the ones in the frontline and the first to be confronted with a deteriorating patient as well. Strengths of this study are the large number of different teams from different backgrounds, augmenting the generalizability of the results of this study.

Other trials in the use of cognitive aids for the surgical population also report improved adherence to best practice.[13,23,28] Cognitive aids for the management of operating room crises reduce omission of critical management steps with 75% to 83%.[13,23] A checklist-based intervention for the postoperative ward round reduced the noncompliance rate with best practice for postoperative complications from 60% to 0%.[37] These studies thus show that adherence to best practice, and potentially patient outcome, can be improved significantly by the use of cognitive aids. The modified early warning score is another valuable tool in preventing failure to rescue in the surgical population,[38] However, it has been shown that the rapid response team is not called in 70% of cases when modified early warning score criteria for activating the rapid response team for critical care input for a deteriorating patient are actually met.[39] Reasons stated are an unclear escalation policy and self-doubt of the attending nurse or physician as well as hierarchical barriers.[7,39] A clear escalation policy on the CAMDS, embraced by all the departments involved, can assist in the timely and uniform escalation of patient care and reduce hierarchical barriers. Designing cognitive aids for deteriorating surgical patients will therefore require support from all the departments involved in the care of these patients. Creating local CAMDS will result in reviewing and improving logistics and protocols regarding the care of these patients, and this process can already improve patient safety.[40] The CAMDS assist in systematically assessing and treating a patient when a diagnosis is made or major symptom is identified. However, there is a risk of fixation error when a team follows a wrong algorithm. This study revealed an incidence of 0.6% of following the wrong algorithm to treat a patient. The design of a cognitive aid can help in preventing fixation error; users should be prompted to explore a differential diagnosis and test the accuracy of their diagnosis. When designing a cognitive aid, it should be taken into account that bad design and lack of training can potentially cause harm by interfering with teamwork or promoting the wrong action or the wrong sequence of actions.[41] A study in the use of a cognitive aid for an emergency surgical airway showed that it took 35.4 seconds longer to achieve oxygenation with a cognitive aid.[42] This emphasizes the point that a cognitive aid should be as clear and concise as possible and only critical steps should be incorporated, especially if the cognitive aid is intended for use during emergencies. Users should be familiar with the cognitive aids when used in clinical practice.[41] In our study, all participants were novices in the use of cognitive aids. It is likely that with better training and familiarity into the use and the limitations of cognitive aids, the effectiveness of the cognitive aids will be improved. Because none of the teams without the cognitive aids were able to effectively use the resources (internet and local protocol database) from the available computer to manage the scenario, there is a probable benefit of hardcopy manuals close to the bed site, in addition to digital versions. Finally, it needs to be emphasized that cognitive aids are tools to assist medical staff, but they by no means replace the need for professional training and involvement of expert help, eg, from critical care staff.

Conclusions

Cognitive aids are tools to improve expert performance. However, despite the potential benefits, the widespread use of cognitive aids in clinical practice is still lacking. This study shows that the use of cognitive aids significantly reduces the number of omitted critical management steps in the treatment of deteriorating patients following surgery. Cognitive aids for deteriorating postoperative patients therefore have the potential to reduce failure to rescue and improve patient outcome. Further research should focus on identifying and targeting barriers to the use of cognitive aids and how to optimize their use in clinical practice.

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Concept and design: Koers, van Haperen, Meijer, Waller, Boermeester, Preckel.
Acquisition, analysis, or interpretation of data: Koers, Meijer, van Wandelen, Waller, Dongelmans, Boermeester, Hermanides, Preckel.
Drafting of the manuscript: Koers, Meijer, Preckel.
Critical revision of the manuscript for important intellectual content: Koers, van Haperen, van Wandelen, Waller, Dongelmans, Boermeester, Hermanides, Preckel.
Statistical analysis: Koers, Hermanides.
Obtained funding: Koers, Boermeester, Preckel.
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Supervision: Koers, Boermeester, Hermanides, Preckel.

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