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Using a clinical decision support system to reduce excess driving pressure: the ALARM trial

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Abstract

Background Patients at need for ventilation often are at risk of acute respiratory distress syndrome (ARDS). Although lung-protective ventilation strategies, including low driving pressure settings, are well known to improve outcomes, clinical practice often diverges from these strategies. A clinical decision support (CDS) system can improve adherence to current guidelines; moreover, the potential of a CDS to enhance adherence can possibly be further increased by combination with a nudge type intervention.

Methods A prospective cohort trial was conducted in patients at risk of ARDS admitted to an intensive care unit (ICU). Patients were assigned to control or intervention by their date of admission: First, the control group was included without changing anything in clinical practice. Next, the CDS was activated showing an alert in the patient data management system if driving pressure exceeded recommended values; additionally, data on the performance of the wards were sent to the healthcare professionals as the nudge intervention. The main hypothesis was that this combined intervention would lead to a significant decrease in excess driving pressure.

Results The 472 included patients (230 in the control group and 242 in the intervention group) consisted of 33% females. The median age was 64 years; median Sequential Organ Failure Assessment score was 8. There was a significant reduction in excess driving pressure in the augmented ventilation modes (0.28 ± 0.67 mbar vs. 0.14 ± 0.45 mbar, $p = 0.012$) but not the controlled mode (0.37 ± 0.83 mbar vs. 0.32 ± 0.8 mbar, $p = 0.53$). However, there was no significant difference between groups in mechanical power, the number of ventilator-free days, or the percentage of patients showing progression to ARDS. Although there was no difference in progression to ARDS, 28-day mortality was higher in the intervention group. Notably, the mean overall driving pressure across both groups was low (12.02 mbar $\pm$ 2.77).

Conclusions In a population at risk of ARDS, a combined intervention of a clinical decision support system and a nudge intervention was shown to reduce the excessive driving pressure above 15 mbar in augmented but not in controlled modes of ventilation.

Keywords Decision support tool, Driving pressure, Critical care, Ventilation

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Background

Ventilator-induced lung injury (VILI) is a major contributor to mortality in patients with acute respiratory distress syndrome (ARDS). To reduce the incidence of VILI and consequently mortality in patients with ARDS, well established treatment strategies such as lung protective ventilation with 6 ml/kg predicted body weight (PBW), as opposed to high tidal volume ventilation, and the use of ventilator driving pressures below 15 mbar have been implemented.[1–6]Indeed, lung-protective ventilation using a low tidal volume reduces the risk of mortality even in patients without ARDS [1–4]. However, although these strategies are considered the standard of care, lung-protective ventilation is only performed in 13.4% of ventilated patients [5]. For patients with less severe lung disease, protective ventilation also potentially decreases the risk of developing ARDS [5–8].

As a tool to increase medical provider adherence to guidelines or local department policy, automated clinical decision support (CDS) systems are being increasingly used in clinical practice [9–11]. A CDS typically provides active support by displaying an alert on the patient's monitor or in the patient documentation system [12].

Another method for successfully influencing the behavior of medical providers is the implementation of nudge interventions, which are designed to avoid "imposing policies or restricting alternative choices" [13]. Educational sessions and frequent emails to providers with feedback on their performance are examples of nudge interventions. There has been little research on the use of nudge interventions or automated alerts to influence practitioners to change ventilator settings in the intensive care unit (ICU), especially for patients at increased risk of developing ARDS [14]. In addition, studies linking these interventions to changes in patient outcomes are lacking. Therefore, the main objective of this study was to show a reduction in driving pressure using a CDS combined with a nudge intervention compared to standard of care.

Methods

Ethical approval and study design

This study was approved by the ethics committee of the University of Vienna (EKNr: 2012/2019) and was registered prior to patient recruitment on clinicaltrials.gov (NCT04274296). A single-center prospective trial with sequential recruitment of a control group and an intervention group was conducted between September 2020 and February 2022. All the included patients or their legal representatives provided consent to participate according to local policies.

Population

Adult patients at risk of developing ARDS admitted to one of six ICUs at the Medical University of Vienna, Austria were evaluated for inclusion in this trial. To predict those patients at risk of ARDS, the lung injury prediction score (LIPS) was developed and validated [15–17]. A LIPS greater than or equal to 4 is associated with a high risk of ARDS [18]. Patients were included if their LIPS at ICU admission was greater than or equal to 4 and if they were ventilated invasively (tube, tracheostomy) at the time of screening. The LIPS was calculated by the treating physicians. This was monitored by the study team which thereby ensured that the LIPS was calculated correctly. The exclusion criteria were pregnancy, ARDS at admission, age < 18 years at admission, and elevated intracranial pressure.

Two cohorts were compared in a pre- and post-interventional study: one underwent treatment with the support of a CDS system and the other underwent treatment without such support. Separation of both groups was achieved by activation of the support system in the pre-existing patient data management system (PDMS) on a certain date: Patients were assigned to one of the two groups based on their admission dates: control phase without CDS (1/9/2020–2/3/2020) and the interventional phase (30/6/2021–4/3/2022) after activation of the CDS. Due to the COVID pandemic at that time and the rapidly changing ICU population with almost all patients being admitted due to ARDS, the trial was stopped for nearly 16 months between the phases and the second phase was extended by 2 months. Except for the activation of alerts by the CDS system and starting the nudge intervention, all treatments were left to the discretion of the treating healthcare providers. There were no major changes in local policies between the two phases, although due to COVID-19, there were two additional nonparticipating intermediate care units that were active during the control phase.

After inclusion, patients were screened daily for moderate to severe ARDS following the Berlin definition [19] (Horowitz Index (PaO2/FiO2) under 200 and correlating chest radiography as decided by a radiologist) by the study team. The PDMS was used to store all study-related data.

Ventilation

Ventilation was at the discretion of the treating staff; no restrictions in ventilatory management were made accept for showing the CDS system. It was provided using either Dräger Evita (Dräger AG, Lübeck, Germany) or Maquet Servo U (Maquet, Rastatt, Germany) respirators. At the included ICUs mainly,

pressure controlled or augmented ventilation modes were used. Therefore, volume controlled or volume-based augmented modes were excluded from the analysis to ensure consistency. Except for BIPAP, all ventilator modes could be unambiguously categorized in either augmented or controlled as the ventilators switched to the augmented mode as soon as the patient had an inspiratory effort (Additional file 1: Table S1). Main goal was to wean patients as fast as possible to augmented ventilator modes. There is no strict standard operation procedure, but the ventilation is set in a patient centered way to ensure optimal ventilation strategies following current guidelines. Sedation and paralyzation was at the physician's discretion. Department policy is that patients are sedated for a minimal period of time and to wean patients from the respirator as soon as possible. Paralyzation is only used if needed during procedures.

Clinical decision support system

In the intervention phase, a clinical advisory alert was shown in the patient data management system (PDMS) (Philips ICCA, Philips, Amsterdam, Netherlands) if the 4-h median driving pressure exceeded 14 mbar and if the limits for permissive hypercapnia and saturation (paCO2: 55 mmHg, pH: 7.25, paO2: 80 mmHg, SaO2: 92%) were exceeded. The alert was shown in the footer of the PDMS; exceeding driving pressures were color coded shown in the usual frontend. Activation of the pre-implemented code was done at the intervention phase's start. The PDMS was used as main application in the ICUs automatically gathering patient care information, such as laboratory data and hourly vitals and observations thereby ensuring that all staff will receive the alert in a timely matter. Furthermore, all ICUs received weekly performance reports including blinded data and their own rank in achievement in reducing driving pressures as the nudge intervention.

Nudge intervention

The nudge intervention included automatically created reports with pseudonymized ranking of all ICUs and data on reductions in driving pressure. These reports were sent biweekly to all physicians and head nurses of every unit and discussed with the teams. A sample report is shown in Additional file 1: Fig. S1. Furthermore, information about the trial and the importance of reducing excess driving pressure was conveyed in an oral presentation to every unit and to all physicians during rounds. In these presentations, possible improvements of ventilator management were discussed including permissive hypercapnia.

Statistical analysis

For sample size planning, a recruitment rate of approximately 250 patients per 6 months was anticipated and power calculation for a two-sample *t*-test showed that 200 patients per group would be sufficient to achieve > 90% at the two-sided 5% significance level under the assumption of a small mean difference in mean excessive driving pressure of 0.33 standard deviations.

Outcome variables were extracted from the PDMS where they are transferred to by the ventilators in an automated fashion.

Metric variables are presented as the mean and standard deviation or the median and interquartile range for, and categorical variables are presented as the absolute and relative frequencies.

The mean driving pressure was calculated as the average of all the driving pressure measurements of a patient during the study period. Excess driving pressure was defined as 0 at time points with driving pressure ≤ 14.9 mbar and as the difference between the current driving pressure and 14.9 mbar otherwise. The mean excess driving pressure was calculated as the average of all the excess driving pressure values for a patient over the study period.

To compare mean driving pressure, mean excessive driving pressure and normally distributed patient characteristics between the control and intervention groups, *t*-tests were used. Right-skewed variables, such as ICU length of stay, were compared between groups using the Wilcoxon rank sum test. Group comparisons for categorical variables were performed using chi-squared tests. $p < 0.05$ was used as threshold for significance.

Results

Patient characteristics

Between September 1, 2020 and March 4, 2022, a total of 2052 patients were screened, among which 175 patients declined to participate. Subsequently, 1405 patients were excluded for the following reasons: a length of stay shorter than 60 min ($n=68$), readmission to the ICU ($n=55$), a LIPS lower than 4 ($n=934$), no mechanical ventilation ($n=185$), ARDS at admission ($n=136$), younger than 18 years ($n=20$), or an ICP ≥ 20 mm of mercury ($n=7$). Ultimately, 472 patients were included in the trial, 230 in the control phase and 242 in the intervention phase (Fig. 1).

Overall, 157 (33%) females and 315 (67%) males were included, in the control group 30% were female; in the

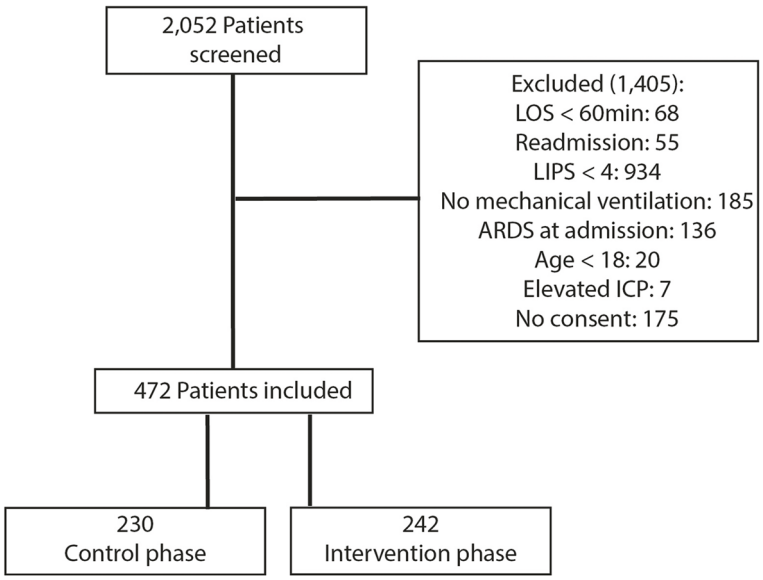

Fig. 1 Patient flowchart. LOS length of stay, LIPS lung injury prediction score, ARDS acute respiratory distress syndrome, ICP intracranial pressure

Table 1 Patient characteristics

	N	All (*n* = 472)	Control group (*n* = 230)	Intervention group (*n* = 242)	*p*
Number of females	472	157 (33%)	68 (30%)	89 (37%)	0.1177*
Age (years)	472	64 (53.75–72)	62 (51.25–71.75)	65 (55–73)	0.0629+
Weight (kg)	469	78 (67–90)	79 (69–90)	75 (65–90)	0.4217+
Height (cm)	439	172 (165.5–180)	173 (167–179.75)	172 (165–180)	0.7347#
Predicted body weight	439	67.7 (58.7–75)	67.7 (61.4–74.1)	67.7 (57.8–75)	0.66+
SAPS3	469	55 (46–65)	55 (44–64)	56 (47–65)	0.15#
Respiratory cause for admission					**0.013°**
ALI or ARDS	472	11 (2.3%)	3 (1.3%)	8 (3.3%)	
COPD	472	9 (1.9%)	4 (1.7%)	5 (2.1%)	
Other	472	58 (12.3%)	18 (7.8%)	40 (16.5%)	
APACHE2	471	18 (14–22)	18 (14–22)	18 (15–22)	0.7154+
SOFA	472	8 (6–10)	8 (6–10)	8 (6–10)	0.4803+
LIPS	468	6.5 (5–8)	6.5 (5–8)	6 (5–8)	0.9256+
Lung transplantation	472	48 (10%)	24 (10%)	24 (10%)	0.9732*

Descriptive statistics are presented as absolute (relative) frequencies or medians (interquartile ranges)

SAPS3 Simplified Acute Physiology Score, *SOFA* Sequential Organ Failure Assessment score, *APACHE2* Acute Physiology and Chronic Health Evaluation, *ALI* acute lung injury, *ARDS* acute respiratory distress syndrome, *COPD* chronic obstructive pulmonary decease, significant values (p<0.05) are shown in bold

* chi-square test

+ Wilcoxon test

t-test

°Kruskal–Wallis

intervention group 37% ($p = 0.12$). There was no statistically significant difference in age (median: 64 years, 53.8–72), LIPS, Simplified Acute Physiology Score (SAPS) (median: 55 (46–65)), or Sequential Organ Failure Assessment (SOFA) score (median: 8 (6–10)) between the two cohorts (Table 1).

Driving pressure

To show the reduction in excessive driving pressure, we first analyzed the driving pressure and excess driving pressure for different ventilation modes. Data from the controlled and augmented ventilation modes were analyzed separately. In the intervention group, patients were

significantly longer in a controlled ventilation mode (30 h (11–73 h) vs. 19 h (10–53.5 h), $p=0.0193$). The same trend was seen for augmented modes but without reaching the predefined level of significance (30 h (4.25–119.5 h) vs. 22.5 h (5–170 h)). For controlled ventilation modes, the overall mean driving pressure was 12.02 ± 2.77 mbar, with a mean excess driving pressure (i.e., excess above 14.9 mbar) of 0.34 ± 0.84 mbar. There were no differences between the control and intervention groups in either the mean driving pressure (12.1 ± 2.81 mbar vs. 11.96 ± 2.75 mbar, *t*-test, $p=0.60$) or the mean excess driving pressure (0.37 ± 0.83 mbar vs. 0.32 ± 0.8 mbar, $p=0.53$). For the augmented ventilation modes, the overall mean driving pressure was 9.01 ± 3.17 mbar, with a mean excess driving pressure above 15 mbar of 0.21 ± 0.57 mbar. There were significant differences between the control and intervention groups in terms of mean driving pressure (9.44 ± 3.2 mbar vs. 8.6 ± 3.08 mbar, $p=0.0067$) and mean excess driving pressure (0.28 ± 0.67 mbar vs. 0.14 ± 0.45 mbar, $p=0.0115$). Results remained unchanged when potential heterogeneity between participating units was taken into account (see Additional file 1: Tables S2 and S3). Figure 2 shows the distribution of hourly measured driving pressures between groups for both ventilation modes. In conclusion, mean driving pressure and mean excessive driving pressure was reduced in the augmented ventilation modes but not in the controlled ventilation modes.

Secondary outcomes

Among the secondary outcomes, only one statistically significant difference was observed—the 28-day mortality rate was significantly higher in the intervention group than in the control group (11% vs. 18%, chi^2, $p=0.034$). Neither ICU mortality (10% vs. 15%, $p=0.14$) nor length of ICU stay (median 166 h vs. 187 h, Wilcoxon test, $p=0.685$) showed significant differences. The percentage of patients showing progression to ARDS was numerically but not significantly smaller in the intervention group (3% vs. 2%, chi^2, $p=0.49$) (Table 2). In summary, a trend towards higher mortality but not higher rates of ARDS was seen in the interventional group.

Paralyzation was uncommon: Rocuronium was needed at least once in 140 patients. In those paralyzed, the median total dose was 100 mg (min: 20 mg, max: 1200 mg) with only 33 patients receiving more than 200 mg in total.

Discussion

Although lung-protective ventilation is known to improve outcomes, adherence to its principles outside controlled trials has been limited [5, 20–22]. Therefore, this trial aimed to introduce a way to reduce excess driving pressure in patients at risk of ARDS. Alerts to the treating healthcare professionals and a nudge intervention led to significant reductions in excessive driving

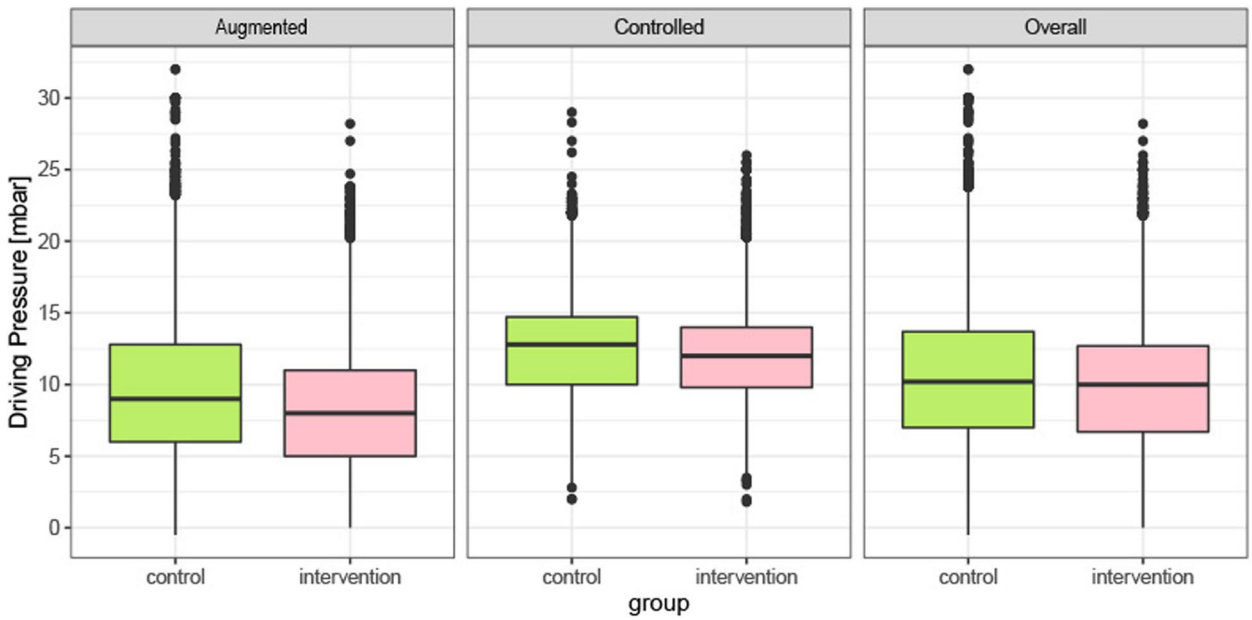

Fig. 2 Driving pressures. The figure shows the distribution of hourly measured driving pressures between groups (control vs. intervention) for augmented and controlled ventilation modes as well as overall

Table 2 Differences in secondary outcomes between the control and intervention groups

	Control ($n=230$)	Intervention ($n=242$)	p value
28-day mortality	25 (11%)	44 (18%)	**0.0342**[*]
ICU mortality	23 (10%)	36 (15%)	0.1391[*]
Progression to ARDS	7 (3%)	4 (2%)	0.4866[*]
ICU LOS (hours)	166 (72–377.75)	187 (85–383)	0.685[+]
Hospital LOS (days)	22 (13–44.75)	24.5 (12.25–42)	0.8875[+]
48-h readmission	4 (2%)	1 (0%)	0.3387[*]
28-day readmission	20 (9%)	13 (5%)	0.2169[*]
Ventilator free days	24 (0–26)	23 (0–26)	0.176[+]
Reintubation	27 (12%)	26 (11%)	0.8442[*]
Time in controlled mode (h)	19 (10–53.5)	30 (11–73)	**0.02**[+]
Time in augmented mode (h)	22.5 (5–170)	30 (4.25–119.5)	0.85[+]

Descriptive statistics are presented as absolute (relative) frequencies or medians (interquartile ranges)

p values less than 0.05 are marked in bold

[*] chi-square test

[+] Wilcoxon test

pressure in the augmented ventilation mode. However, no differences in excessive driving pressure were detected in the controlled ventilation modes.

Despite previous reports of poor adherence to lung-protective ventilation strategies, the healthcare professionals in this study adhered to lung-protective ventilation even for the control group [5, 22]. This difference cannot be explained by clinician bias: Data were collected from this group prospectively, but the treating staff was not informed about the collection to ensure a clean pre-intervention cohort. Nonetheless, similar results were recently shown by another group, indicating a possible shift in clinical practice towards a more broad use of low driving pressures [23]. This already existing trend towards better adherence indeed decreases the possible effect of behavioral correction efforts.

This study shows that excessive driving pressure could be reduced by alerts in patients on augmented but not on controlled ventilation. Overall mean driving pressure during controlled ventilation was below 15 mbar. Therefore, in a large proportion of those patients, no alert was shown. Another possible explanation for this finding could be that patients were ventilated in the augmented mode most of the time as it is common practice at the study sites to wean ICU patients as quickly as possible. Third, it is typically easier to reduce the driving pressure in augmented ventilation modes because patients in the weaning process can often compensate the lowered support.

When looking at the secondary outcomes, which were not corrected for multiple testing, no significant difference in the percentage of patients showing progression to ARDS or the number of ventilator-free days was detected. Interestingly, the 28-day mortality rate was higher in the intervention group although length of hospital stay was not significantly different between the two groups. One reason can be found in the patient characteristics: In the interventional phase significantly more patients were admitted due to respiratory reasons. This could be an explanation for the longer duration of ventilation in the interventional group. The difference in patients admitted due to respiratory causes can be explained by two temporary intermediate care wards (not taking part in the trial) being in place due to COVID-19.

While ICU mortality was not significantly different between the groups, mortality at day 28 was. This could be pointing towards a slightly different case mix in the intervention group although all scores and baseline characteristics except reason for admission were the same. To elaborate this thought, a supplemental analysis was done (Additional file 1: Table S4). After correction for SAPS3, no significant difference regarding 28-day mortality could be seen although the higher p value could also be due to minimally increased uncertainty.

A causal association with the intervention seems unlikely, especially as there was no difference in the percentage of patients who showed progression to ARDS. This noncausal association is further reinforced by the lack of a difference in ICU mortality rates.

Limitations

There are some relevant limitations regarding this trial. First, it was a single-center trial, and the treating staff played an important role, which possibly introduced bias. Another limitation is the unplanned suspension of the trial due to the spread of COVID-19. Recruitment was stopped between the two phases and the interventional phase was extended by 2 months, as only a

very low number of surgical (non-ARDS) patients were treated during that time, possibly introducing bias, as seasonal changes (i.e., the flu or lower numbers of surgeries during the summer holidays) in patient characteristics could not be excluded as planned. This most probably leads to the higher proportion of respiratory causes for ICU admission in the intervention phase. Furthermore, to correctly calculate the driving pressure in the modes mentioned, the pleural pressure needs to be measured [24], which was not routinely performed for those patients.

Calculating driving pressure in pressure controlled or even augmented ventilation is a difficult task [25]. To calculate absolute values, static measurements are needed often requiring esophageal pressure probes. Those are typically not available in a routine clinical setting—especially in patients "only" at risk of ARDS. Therefore and to aid generalizability of the results, we decided to calculate driving pressure by subtracting PEEP from peak pressure. As the main outcome was reduction in excessive driving pressure and by assuming that the transpulmonary pressure was equally distributed, the need for those values was reduced. Furthermore, a sensitivity analysis in patients where compliance was available showed that in 74% of cases this value differed by less than 2 mbar from a value calculated by tidal volume/compliance. This shows that the driving pressure calculations should not influence the reduction in excessive driving pressure to a large extend, but one has so acknowledge that this way of calculating driving pressure will introduce bias.

Unfortunately, no information about the causes of death after discharge from ICU was available leaving a small uncertainty about the higher 28-day mortality in the intervention group.

In contrast to some other studies like Amato et al., the reported driving pressure values are reported in mbar rather than in cmH2O. [20] As the respirators used report the pressure values in the SI unit mbar, and due to the small difference, we used these values and did not convert to cmH2O (1 cmH2O = 0.98 mbar). A cut-off of 14 mbar (14.3 cmH2O) was chosen to ensure that the alert is safely triggered below 15 cmH2O which was shown to be the relevant cut-off [20].

This trial consisted of a combined intervention of a CDC and a nudge intervention. The ventilator settings were at the treating staffs discretions; both nurses and physicians were allowed to manipulate the ventilator settings—and both received the nudge intervention. Therefore, it is difficult to differentiate whether a change in respirator settings was due to the alert or not. The study design as a controlled trial should reduce this possible bias although it cannot fully exclude it.

Conclusions

In a population at risk of ARDS, a combined intervention of a clinical decision support system and a nudge intervention was shown to reduce the excessive driving pressure above 14 mbar in augmented but not in controlled modes of ventilation. This shows an opportunity of further increasing the adherence to protective ventilation guidelines by introducing behavioral measures and therefore possibly preventing progression to ARDS.

Abbreviations

ARDS	Acute respiratory distress syndrome
CDS	Clinical decision support
ICU	Intensive care unit
LIPS	Lung injury prediction score
PBW	Predicted body weight
PDMS	Patient data management system
VILI	Ventilator-induced lung injury

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12916-025-03898-2.

Additional file 1: Tables S1–S4, Figure S1. The file includes additional information on the classification of ventilation modes as well as a sample report used in the nudge intervention. Furthermore additional analysis was done for both driving pressure and mortality. Table S1 Classification of ventilation modes. Fig. S1. Sample report. Table S2. Linear mixed model analysis of mean differences of mean driving pressure and mean excessive driving pressure. Table S3. Linear mixed model analysis of mean differences of mean driving pressure and mean excessive driving pressure with adjustment for SAPS3 score. Table S4. Logistic mixed effects model regression model for 28-day mortality.

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Authors' contributions

Concept and design: MM, UBK, RU. Acquisition of data: MM, UBK, RU, MR. Statistical Analysis:RR, BK. Interpretation of data: MM, UBK, RU, CK, RR, BK, MR. Drafting of the manuscript: MM, UBK, RU, CK, RR, BK Critical revision of the manuscript for importantt intellectual content: MM, UBK, RU, CK, RR, BK, MR.

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Data availability

The datasets used and/or analyzed during the current study as well as the used code are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the ethics committee of the University of Vienna (EKNr: 2012/2019) and was registered prior to patient recruitment on clinicaltrials.gov (NCT04274296). All the included patients or their legal representatives provided consent to participate according to local policies.

Consent for publication

All authors consented to publication of this paper.

Competing interests

The authors declare no competing interests.

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