



Published in final edited form as:

J Crit Care. 2018 April ; 44: 191–195. doi:10.1016/j.jcrc.2017.11.014.

A modified Montpellier protocol for intubating intensive care unit patients is associated with an increase in first-pass intubation success and fewer complications

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Abstract

Background: The Montpellier protocol for intubating patients in the intensive care unit (ICU) is associated with a decrease in intubation-related complications. We sought to determine if implementation of a simplified version of the Montpellier protocol that removed selected components and allowed for a variety of pre-oxygenation modalities increased first-pass intubation success and reduced intubation-related complications.

Methods: A prospective pre/post-comparison of a modified Montpellier protocol in two medical and one medical/surgical/cardiac ICU within a hospital system. The modified eight-point protocol included: fluid administration, ordering sedation, two intubation trained providers, pre-oxygenation with non-invasive positive pressure ventilation, nasal high flow cannula or non-rebreather mask, rapid sequence intubation, capnography, sedation administration, and vasopressors for shock.

Results: Patient characteristics and indications for intubation were similar for the 275 intubations in the control (137) and intervention (138) periods. In the intervention vs. control periods, the modified Montpellier protocol was associated with a significant 16.2% [95% CI: 5.1–30.0%]

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Author's contributions

KC: study concept and design, patient enrollment, staff education, data entry analysis and interpretation, drafting and revision of manuscript; CD: study design, patient enrollment, staff education, data entry and revision of manuscript; AA: data entry and revision of manuscript; NA: patient enrollment, data entry and revision of manuscript; TA: study design, patient enrollment, staff education, data entry and revision of manuscript; SM: data analysis and interpretation, drafting and revision of manuscript; RM: study design, data analysis and interpretation, drafting and revision of manuscript; ML: study design, data interpretation, and revision of manuscript; JA: study design, patient enrollment, staff education, data interpretation and revision of manuscript.

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jcrc.2017.11.014>.

Competing interests

No authors have any competing interests.

increase in first-pass intubation success and a 12.6% [95% CI: 1.2–23.6%] reduction in all intubation-related complications.

Conclusion: A simplified version of the Montpellier intubation protocol for intubating ICU patients was associated with an improvement in first-pass intubation success rates and a reduction in the rate of intubation-related complications.

Keywords

Intubation; Intensive care unit; Intubation complications; First-pass success; Montpellier protocol

1. Introduction

Endotracheal intubation is one of the most frequently performed procedures in the intensive care unit (ICU) and is associated with a high incidence of complications (27–39%) [1-3]. Although the specialties of anesthesiology and emergency medicine have produced guidelines and research aimed at reducing intubation-related complications [4,5] relatively few interventions have targeted these complications in the ICU setting [6,7]. Successfully intubating on the first attempt, termed first-pass intubation success, is associated with a reduction of intubation-related complications [8-10]. Jaber et al. demonstrated that their Montpellier protocol for intubating the critically ill is associated with an absolute reduction in moderate and severe intubation-related complications [6]. The Montpellier protocol outlines ten points for pre-, intra-, and post-intubation care in the ICU that includes intravenous fluid (IVF) administration, pre-oxygenation, and rapid sequence intubation (RSI). However, the clinical utility of some of the elements of the protocol, such as application of the Sellick maneuver, has been questioned [11]. Other elements, such as lung protective strategy, have well established benefits for ventilator-associated patient outcomes [12], but are unlikely to impact intubation-related complications. In addition, elements such as mandatory pre-oxygenation with non-invasive positive pressure ventilation (NIPPV) present logistical challenges and are not easily utilized for all critically ill patients.

We conducted a prospective, pre/post-comparison investigation of the impact of a hospital system-wide intubation protocol for intubating critically ill ICU patients. We hypothesized that, as compared to usual ICU intubation practice, a simplified Montpellier protocol that removed the Sellick maneuver, allowed for a variety of pre-oxygenation modalities, and eliminated post-intubation ventilator management would increase first-pass intubation success and decrease intubation-related complications.

2. Methods

2.1. Study design and setting

This investigation of a pre/post-comparison of the impact of an intubation protocol (a modified Montpellier protocol) was conducted over a thirteen-month period between April 1st, 2016 and April 30th, 2017. The initiative was implemented at three ICUs within the same hospital system: an 18-bed medical ICU, an 18-bed step-down ICU, and a 16-bed combined medical, surgical, and cardiac ICU. The study consisted of a six-month pre-implementation (hereafter: control) period, followed by a one-month protocol

education period, and ended with a six-month post-implementation (hereafter: intervention) period. The study was approved by the hospital's institutional review board as a quality improvement initiative and a waiver of informed consent was obtained.

2.2. Intubation quality improvement intervention (the modified Montpellier protocol)

The original 10-point Montpellier protocol was modified to an 8-point protocol: four pre-, one intra-, and three post-intubation components (Supplementary Fig. 1). We eliminated the Sellick maneuver and post-intubation ventilator management components present in the original Montpellier protocol. We expanded the mechanisms for pre-oxygenation allowing for use of: [1] NIPPV with 10/5 cm H₂O using 100% FiO₂; [2] high flow nasal cannula at 40 L/min using 100% FiO₂; or [3] application of a non-rebreather mask with O₂ above 15 L/min to allow for maximum oxygen flow (also known as “flush rate” flow). A summary of the other components required in the modified Montpellier protocol is as follows: intravenous fluids (IVFs) were to be administered prior to intubation via a bolus of 500 mL of crystalloid (normal saline or lactate ringers) at a rate of >500 mL/h, unless clinically contraindicated. We required the fluid bolus be initiated but did not require that it be completed prior to intubation. Preparation of long-term sedation with an order for a sedative hypnotic (propofol, dexmedetomidine, ketamine, midazolam and fentanyl) placed in the electronic medical record prior to intubation. Two intubation trained providers must be present. RSI, including both the administration of a sedative hypnotic (etomidate, propofol, dexmedetomidine, ketamine, midazolam and fentanyl, or phenobarbital) and a neuromuscular blocking agent (succinylcholine, rocuronium, or atracurium) at dosing determined by the physicians performing the intubation. Post-intubation sedation included any sedative administered within 30 min of the intubation. Capnography, using the hospital's disposable colorimetric device with presence of adequate carbon dioxide levels confirmed by visual inspection. Vasopressors (norepinephrine, epinephrine, vasopressin, dopamine or phenylephrine) used for post-intubation hypotension and initiated within 15 min for patients with a mean arterial pressure (MAP) <65 mm Hg.

During the 6-month control period, intubations in the ICU were performed as per usual care. The intervention was implemented during a one-month protocol education period across all study ICUs. All ICU attending physicians, fellows, advanced practice providers, nurses and respiratory therapists were educated on the modified Montpellier protocol through a 30-minute in-person presentation. Residents were educated on the protocol by the attending physicians and fellows as part of their orientation to ICU each month. All staff were informed they should implement the protocol for all intubations in the ICU during the intervention period. During the control and intervention periods of the study, physicians performing intubations completed a data form on what procedures were followed before, during, and after the intubation (Supplementary Fig. 2).

2.3. Intervention outcome assessment

Impact of the intervention was assessed by comparing information collected from the intubation data form completed by physician staff and review of the ICU electronic medical records of those intubations by the study investigators. These two data sources were compiled for each intubation. Compiled data from the six-month intervention period

were compared to the six-month control period in aggregate. Measured outcomes included adherence to each modified Montpellier intubation protocol component, first-pass intubation success rates, and complications potentially related to the intubation (i.e., adverse events not present prior to intubation). Major complications were defined as death, cardiac arrest, severe hypoxemia (oxygen saturation < 80%), or persistent shock (a MAP <65 mm Hg or systolic blood pressure < 90 mm Hg for >30 min). Minor complications were defined as cardiac arrhythmia (other than sinus tachycardia), vomiting without aspiration, aspiration (visualizing vomitus in the airway), dental injury, esophageal intubation, or a difficult intubation (three or more intubation attempts or any attempt requiring anesthesia assistance).

2.4. Statistical analysis

Categorical variables were expressed in terms of proportions. Depending on the normality of their distribution, continuous variables were described by either the mean and standard deviation or median and interquartile range. Either Fisher's exact tests or chi-square tests were used to compare categorical variables, as appropriate. Confidence intervals for differences in proportions were calculated using Agresti-Caffo intervals. Student's *t*-tests were used for comparisons with normal continuous variables and Wilcoxon score tests were used for comparison of non-normally distributed variables, as appropriate. Differences in medians were computed using the Hodges Lehmann estimator. All analyses were performed using SAS 9.4 (SAS Institute, Cary, NC).

3. Results

3.1. Patient and intubation characteristics

For the pre-implementation (control) and post-implementation (intervention) periods, 275 intubations were recorded for 253 hospital stays; 137 in the control and 138 in the intervention period. Table 1 illustrates patient demographic characteristics, clinical characteristics, and reasons for ICU admission for the intervention vs. control periods. Patient characteristics were similar except for a higher proportion of obstructive sleep apnea in the control period and an average 2.8-point lower APACHE II score in the intervention period. Indications for and the methods of intubation were similar for the two periods (Table 2). More fellows and fewer residents and anesthesiology staff (attending physicians or anesthesiologists) performed intubations in the intervention period (Table 3).

3.2. Protocol adherence

Administration of IVFs, pre-oxygenation, use of RSI, and the ordering and administration of patient sedation all were greatly increased in the intervention period (Table 4). There were no statistically significant changes in the use of capnography, vasopressors, or the presence of two or more intubation trained providers. The total number of protocol elements executed per intubation increased in the intervention vs. control period, from 44.5% of intubations during the control to 80.4% during the intervention period demonstrating adherence to 75% of protocol components (Table 5).

3.3. First-pass intubation success and intubation-related complications

First-pass intubation success rates improved 16.2% [CI 95%: 5.1–30.0%] from the control to the intervention period (Table 6). All intubation-related complications decreased by 12.6% [CI 95%: 1.2–23.6%]. A stratified analysis showed that although major complications decreased from 21.8% to 13.8% and minor complications from 31.4% to 21.7%, the differences did not reach statistical significance. There were no differences between ICU length-of-stay, hospital length-of-stay, or survival-to-discharge between the intervention and control periods. A secondary analysis of adherence to bundle components and outcomes by patient indication for intubation showed similar trends in first pass success and complications, but was limited by sample size (Supplemental Table 1).

4. Discussion

The results of this investigation show that implementation of a modified Montpellier protocol to guide intubation in the ICU is associated with an increase in first-pass intubation success rates and a decrease in all intubation-related (major and minor) complications. Our experience demonstrates that this simplified intervention can be implemented easily after a short educational training session, readily adopted, reasonably adhered to, and can quickly yield improvements over usual intubation practice in the ICU.

First-pass intubation success rate is an important indicator of quality improvement for intubation, and has been associated with a lower rate of intubation-related complications in multiple studies [9,13,14]. A 2004 analysis of over 2800 non-operative intubations, of which 69% were in an ICU setting (medical, surgical, trauma, cardiac or neurologic), showed that 3 intubation attempts were associated with a 4-fold increase in aspiration, a 14-fold increase in severe hypoxemia, and a 7-fold increase in death [14]. These findings were corroborated by an emergency department-based study that found that more than one intubation attempt was associated with a 7.5 odds ratio increase of an adverse event [9]. Based on these data, and the results of our study, achieving a higher first-pass intubation success rate is a crucial goal when intubating a critically ill patient. Our observed increase in first-pass success is likely secondary to the significant increase (26.5%) in the use of RSI, a phenomena observed by other authors [5]. It is also possible that a larger number of fellows making the first intubation attempt in the intervention arm increased first-pass success. No other protocol element would be expected to influence first-pass success rates.

Commensurate with the improvement in first-pass intubation success rate, we observed a 12.6% [CI 95%: 1.2–23.6%] absolute decrease in combined major and minor complications, which is similar to the drop in moderate (12%) and severe complications (13%) seen with the original Montpellier protocol [6]. While the rates of IVF administration, pre-oxygenation, RSI and sedation ordering and administration all increased markedly from the control to intervention period, endotracheal tube placement confirmation with capnography and administration of vasopressors for shock were unchanged due to their near universal implementation prior to the intervention (>97%). The presence of more than one provider trained in intubation techniques has been associated with reduced complications [15]. Our proportion of intubations having two providers capable of performing intubation remained unchanged throughout the study (74–77%) and hence indicates room for improvement.

Although causation cannot be determined from this investigation, the lack of change from the control to intervention period in these components suggests that they contributed less to the observed improvement in first-pass intubation success rates or reduction in complications.

In an effort to simplify and update the original Montpellier intubation protocol, we eliminated the Sellick maneuver and the post intubation mechanical ventilation components, and permitted more options for pre-oxygenation. The Sellick maneuver, more accurately described as direct cricoid pressure, is thought to provide a secondary safeguard against gastric regurgitation by occluding the esophagus proximal the lower esophageal sphincter. Contemporary research suggests that it fails to prevent aspiration of stomach contents and may potentially limit optimal visualization during intubation [11]. Direct cricoid pressure was therefore eliminated from the protocol, but providers were allowed to perform external cricoid manipulation to improve airway visualization. Increasing pre-oxygenation options allowed for a pragmatic and patient tailored approach to pre-oxygenation that did not compromise efficacy. Our post-implementation rate of severe hypoxemia (9.5%) is similar to the rate reported with the original Montpellier protocol (10%) [6]. There are a variety of means to pre-oxygenate a patient prior to intubation and the clinical superiority of any modality remains debated. High flow nasal cannula is an appropriate alternative to NIPPV for managing patients with hypoxic respiratory failure in the ICU [16]. A randomized trial showed that NIPPV was superior to pre-oxygenation with a nonrebreather mask for prevention of severe hypoxemia during intubation [17]. However, trials comparing high flow nasal cannula to nonrebreather pre-oxygenation have produced mixed results [18,19]. Of importance, these trials compare nonrebreather oxygen flow rates of 10–15 L/min to NIPPV and high flow nasal cannula. Standard medical oxygen flow meters are capable of delivering significantly higher oxygen flow rates (48 L/min) with standard face masks [20]. A recently published study suggests that a nonrebreather mask coupled with O₂ above 15 L/min, to allow for maximum oxygen flow (flush rate flow), can provide a level of pre-oxygenation equivalent to bag mouth ventilation [21]. The ability to select between three modalities for pre-oxygenation makes our modified protocol more easily adapted by institutions with varying resources and applied to patients with a wider spectrum of pathology.

Our study has a number of limitations. Chief among these is that the pre/post assessment study design is not sufficient to prove causality; measured outcomes can only be associated with the study intervention. It is possible that observed effects were a product of differences in patients, changing trends in care, greater experience by ICU staff, increased training, and the pool of clinicians performing the intubation. To compensate for this changing pool and experience, we intentionally began enrollment in April so as to include a pre-intervention group of residents and fellows in their final three months and the following first three months of the academic training year. Likewise, the post-intervention group of clinicians consisted of residents and fellows in the middle six months of the academic year. Nevertheless, a greater number of fellows and fewer residents or anesthesiologists intubated in the post-intervention period. This phenomenon may have been product of protocol implementation or it may have been an independent event with the potential to influence the observed results. A second limitation is that an intervention group with 100% adherence to the Modified Montpellier protocol was not assured. While this reflects a

pragmatic reality of conducting a study with this design, the study results may understate the true effect of the protocol. Additionally, our study did not involve an evaluation of the original Montpellier protocol absent our modifications. As a result we cannot determine the impact of the elements we changed or excluded. Another limitation is that the intubation events were captured and complications were obtained in part using a self-report form. It is possible that physicians avoided reporting an intubation that resulted in a poor patient outcome. This action could have introduced reporting bias; however, our rates of major and minor complications are comparable to the original Montpellier trial [6]. Finally, evaluating the interventions as a bundle severely limits the ability to draw any conclusions on the value of any individual bundle component.

5. Conclusion

A simplified version of the Montpellier intubation protocol for intubating ICU patients was associated with an improvement in first-pass intubation success rates and a reduction in the rate of all intubation-related complications. Further efforts are needed to assess the contribution and value of individual intubation protocol elements.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements

We would like to extend a special thanks to the residents, fellows, nurses and respiratory therapists who work in the ICU and made this study possible.

Funding

This project was supported by the Division of Pulmonary and Critical Care and the Department of Emergency Medicine, Alpert Medical School of Brown University and the Graduate Medical Education Center Award to Support Quality and Research Projects, cost-center: 101-6484.

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Table 1

Patient characteristics for the pre-implementation (control) and post-implementation (intervention) periods.

	Control period mean (SD)(n = 130)	Intervention period mean (SD)(n = 123)	p-Value
Age in years	61.7 (15.2)	62.9 (14.7)	0.54
BMI	31.2 (9.2)	29.2 (10.9)	0.12
APACHE II	25.9 (7.6)	23.1 (8.2)	0.01
Female gender ^a	73 (56.2)	70 (56.9)	1.00
	N (%)	N (%)	
Prior medical history			
Congestive heart failure	41 (31.5)	27 (22)	0.09
Chronic kidney disease	31 (23.8)	20 (16.3)	0.16
COPD	30 (23.1)	25 (20.3)	0.65
Chronic liver disease	20 (15.4)	16 (13)	0.72
Active malignancy	19 (14.6)	19 (15.5)	0.86
Obstructive sleep apnea	18 (13.8)	7 (5.7)	0.04
Diabetes with organ damage	16 (12.3)	16 (13)	1.00
Myocardial infarction	15 (11.5)	17 (13.8)	0.71
Cerebrovascular accident	8 (6.2)	12 (9.8)	0.35
Reason for MICU admission			0.35
Acute respiratory failure	84 (64.6)	69 (56.1)	
Other: GI, hematologic, metabolic, alcohol/substance abuse ^b	14 (10.8)	13 (10.6)	
Sepsis/septic shock	13 (10)	14 (11.4)	
Shock (not septic)	8 (6.2)	6 (4.9)	
Cardiac	6 (4.6)	8 (6.5)	
Neurologic	5 (3.8)	13 (10.6)	

APACHE II Acute Physiology and Chronic Health Evaluation II, *BMI* body mass index, *COPD* chronic obstructive pulmonary disease, *GI* gastrointestinal, *N* number.

^aN (%).

^bIn other, GI: 3 control, 4 intervention; hematologic: 1 control, 1 intervention; metabolic: 6 control, 3 intervention; alcohol/substance abuse: 4 control, 5 intervention.

Table 2

Indications for and methods used during intubation.

	Control period N (%) (n = 137)	Intervention period N (%) (n = 138)	p-Value
Indication for intubation			0.94
Hypoxemia	53 (38.7)	46 (33.3)	
Hypercarbia	24 (17.5)	27 (19.6)	
Mixed hypoxemia, hypercapnia	24 (17.5)	25 (18.1)	
Airway protection	13 (9.5)	16 (11.6)	
Cardiac arrest	7 (5.1)	9 (6.5)	
Altered mental status	7 (5.1)	8 (5.8)	
Pre-procedural	7 (5.1)	4 (2.9)	
Other	2 (1.5)	3 (2.2)	
Method used in successful intubation attempt			0.17
Video	80 (58.4)	69 (50)	
Direct	54 (39.4)	68 (49.3)	
Bronchoscopic	2 (1.5)	0 (0)	
LMA	0 (0)	1 (0.7)	
Surgical	1 (0.7)	0 (0)	

LMA Laryngeal Mask Airway.

Table 3

Characteristics of providers performing intubations.

	Control period N (%) (n = 131) ^a	Intervention period N (%) (n = 132)	p-Value
Provider performing successful intubation			<0.01
Fellow	68 (51.9)	94 (71.2)	
Resident	30 (22.9)	15 (11.4)	
Anesthesiologist	14 (10.7)	8 (6.1)	
Hospitalist	12 (9.2)	4 (3)	
Other	5 (3.8)	5 (3.8)	
Pulmonary/critical care attending	2 (1.5)	6 (4.5)	
Provider making first intubation attempt ^b			<0.01
Fellow	61 (47.3)	90 (68.2)	
Resident	42 (32.6)	23 (17.4)	
Hospitalist	14 (10.9)	5 (3.8)	
Anesthesiologist	7 (5.4)	7 (5.3)	
Other	5 (3.8)	4 (3.0)	
Pulmonary/critical care attending	0	3 (2.3)	
Resident involved at any time	47 (34.3)	24 (17.4)	<0.01
Fellow involved at any time	74 (54.0)	100 (72.5)	<0.01
Attending involved at any time	17 (12.4)	12 (8.7)	0.33

^aMissing data for 12 cases (six pre and six post implementation cases).^bMissing data for 2 cases for whom performed the first intubation.

Table 4

Changes in adherence to protocol components.

	Control period N (%) (n = 137)	Intervention period N (%) (n = 138)	Absolute change % (95% CI)	p-Value
Pre-intubation				
1 Two or more capable intubators	106 (77.4)	102 (73.9)	-3.5 (-13.6, 6.6)	0.57
2 IV fluids administered	59 (43.1)	111 (80.4)	37.4 (26.8, 48)	<0.0001
3 Sedation ordered	78 (55.9)	114 (82.6)	25.7 (15.3, 36.1)	<0.0001
4 Pre-oxygenation with NIPPV, HFNC, or non-rebreather	72 (52.6)	98 (71.0)	18.5 (7.2, 29.8)	<0.01
Intubation				
5 RSI	66 (48.2)	103 (74.6)	26.5 (15.4, 37.6)	<0.0001
Post-intubation				
6 Capnography	134 (97.8)	136 (98.6)	0.7 (-2.5, 3.9)	0.68
7 Appropriate use of vasopressors for shock (MAP < 65 mm Hg)	133 (97.1)	138 (100.0)	2.9 (0, 5.7)	0.06
8 Sedation administered	80 (58.4)	118 (85.5)	27.1 (17, 37.2)	<0.0001

IV Intravenous, HFNC high flow nasal cannula, MAP mean arterial pressure, mm Hg millimeters mercury, NIPPV non-invasive positive pressure ventilation, RSI rapid sequence intubation.

Table 5

Intervention adherence by total number of protocol components.

Number of components	Control period n (%) (n = 137)	Intervention period n (%) (n = 138)	Absolute change %
1	0 (0)	0 (0)	–
2	5 (3.7)	1 (0.7)	–3.7
3	11(8.0)	1 (0.7)	–7.3
4	21 (15.3)	7 (5.1)	–10.2
5	39 (28.5)	18 (13.0)	–15.5
6	28 (20.4)	21 (15.2)	–5.2
7	26 (19.0)	49 (35.5)	16.5
8	7 (5.1)	41 (29.7)	24.6

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Table 6

Intubation and patient level outcomes.

Intubation outcome	Control period N (%) (n = 137)	Intervention period N (%) (n = 138)	Absolute change % (95% CI)	p-Value
Successful first pass intubation ^a	80 (58.4)	103 (74.6)	16.2 (5.1, 30.1)	<0.01
More than one provider attempted intubation	30 (21.9)	19 (13.8)	-8.1 (-17.0, 1.0)	0.08
All complications	59 (43.1)	42 (30.4)	-12.6 (-23.6, -1.2)	0.03
Major complications	29 (21.2)	18 (13)	-8.1 (-16.9, 0.9)	0.08
New sustained shock	7 (5.1)	5 (3.6)	-1.5 (-6.6, 3.7)	0.57
New severe hypoxemia	20 (14.6)	13 (9.4)	-5.2 (-12.9, 2.7)	0.20
Death/cardiac arrest	2 (1.5)	1 (0.7)	-0.7 (-3.8, 2.4)	0.62
Minor complications	43 (31.4)	30 (21.7)	-9.7 (-19.9, 0.8)	0.08
Arrhythmia	4 (2.9)	3 (2.2)	-0.8(-4.9, 3.4)	0.72
Aspiration	4 (2.9)	8 (5.8)	2.9 (-2.3, 8.0)	0.38
Vomiting without aspiration	4 (2.9)	2 (1.5)	-1.5 (-5.4, 2.5)	1.00
Dental injury	0 (0)	1 (0.7)	0.7 (-1.7, 3.2)	0.44
Esophageal intubation	9 (6.6)	6 (4.3)	-2.2 (-7.8, 3.4)	0.45
Difficult intubation	24 (17.5)	15 (10.9)	-6.7 (-114.8, 1.7)	0.12
Patient outcomes	Control period N (%) / median (IQR) (n = 130)	Intervention period N (%) / median (IQR) (n = 123)	Absolute change % (95% CI)	p-Value
Hospital length of stay	12 (7-20)	11 (6-20)	-1 (-3, 2)	0.55
ICU length of stay	7 (4-13)	7 (3-13)	0 (-2, 1)	0.89
Discharged alive	74 (56.9)	72 (58.5)	3.9 (-7.7, 15.5)	0.54

^aTwo attempts required in 31.4% of control period intubations and 19.6% in intervention period; three attempts required in 8.0% of control period intubations and 4.4% in intervention period, four or more attempts required in 2.1% of control period intubations and 1.4% in intervention period.