Table 3. Clinical outcomes and adverse events

Characteristic	Intervention	Control	Effect size (95% CI)	*P* value
Clinical outcomes (intention-to-treat population)				
	n=97	**n=93**	**Adj RR (95% CI)**	
Ventilator associated pneumonia and aspiration pneumonia, no. (%)	21 (22.6)	20 (22.7)	0.99 (0.58–1.70)	0.984[a]
Acute respiratory distress syndrome, no. (%)	3 (3.2)	5 (5.7)	0.58 (0.14–2.32)	0.431[a]
Mortality in ICU, no. (%)	14 (15.4)	11 (13.3)	1.17 (0.56–2.42)	0.682[a]
Mortality on discharge, no. (%)	24 (25.8)	21 (23.9)	1.08 (0.65–1.79)	0.770[a]
Died in ED	1 (1.1)	4 (4.5)		
Died on discharge	23 (24.7)	17 (19.3)		
Number of ventilated days			**Median diff (95% CI)**	0.381[b]
Median (Q1, Q3)	2.0 (1.0, 5.0)	2.0 (1.0, 5.0)	0 (-1.0, 1.0)	
Length of stay in ICU, days				
Median (Q1, Q3)	4.0 (2.0, 7.0)	3.0 (2.0, 8.0)	1.0 (-1.0, 2.0)	0.615[b]
Highest SOFA score				
Median (Q1, Q3)	7.0 (5.0, 10.0)	8.0 (6.0, 11.0)	-1.0 (-2.0, 0)	0.112[b]
Adverse events (as-treated population)				
	n=92	**n=98**	**Adj RR (95% CI)**	
Patients with any peri-intubation adverse events	17 (18.5)	13 (13.3)	1.39 (0.72, 2.71)	0.426[b]
Type of peri-intubation adverse events[d]				
Aspiration	1 (1.1)	0 (0)	NA	0.484[c]
Bradycardia	2 (2.2)	3 (3.1)	0.71 (0.12, 4.15)	1.000[c]
Cardiac arrest	3 (3.3)	1 (1.0)	3.20 (0.34, 30.17)	0.356[c]
Cardiac arrhythmia	0 (0)	3 (3.1)	NA	0.247[c]
Hypertension	4 (4.3)	5 (5.1)	0.85 (0.24, 3.08)	1.000[c]
Hypotension	4 (4.3)	3 (3.1)	1.42 (0.33, 6.18)	0.714[c]
Oropharynx or dental trauma	0 (0)	2 (2.0)	NA	0.498[c]
Regurgitation	0 (0)	0 (0)	NA	1.000[c]
Tachycardia	4 (4.3)	2 (2.0)	2.13 (0.40, 11.36)	0.433[c]
Others	0 (0)	0 (0)	NA	1.000[c]
Action taken to study treatment				
Continued with allocated group	15 (16.3)	13 (13.3)		
Changed to other oxygenation techniques	1 (1.1)	0 (0)		
Adverse events caused patient to be discontinued from study	0	0		

Adj RR: adjusted relative risk; CI: confidence interval; ED: emergency department; ICU: intensive care unit; median diff: median difference; NA: not available; Q1: 25th percentile; Q3: 75th percentile; SOFA: Sequential Organ Failure Assessment

[a] *P* value from van Elteren test

[b] *P* value from Cochran-Mantel-Haenszel test

[c] For number of events <10, Fisher's Exact test was used instead of Cochran-Mantel-Haenszel test

[d] Peri-intubation adverse events (occurring during or within 5 minutes after intubation) were defined as: bradycardia (defined as heart rate <60 beats per minute or decrease by >20%); tachycardia (defined as heart rate >100 beats per minute or increase by >20%); hypotension (defined as systolic blood pressure <90mmHg or decrease by >20%); hypertension (defined as systolic blood pressure >140mmHg or increase by >20%)