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1-hour t-piece spontaneous breathing trial vs 1-hour zero pressure support spontaneous breathing trial and reintubation at day 7: A non-inferiority approach

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ABSTRACT

Purpose: Physiological data suggest that T-piece and zero pressure support (PS0) ventilation both accurately reflect spontaneous breathing conditions after extubation. These two types of spontaneous breathing trials (SBTs) are used in our Intensive Care Unit to evaluate patients for extubation readiness and success but have rarely been compared in clinical studies.

Materials and methods: We performed a prospective observational study to confirm the hypothesis that 1-hour T-piece SBT and 1-h PS0 zero PEEP (ZEEP) SBT are associated with similar rates of reintubation at day 7 after extubation. A non-inferiority approach was used for sample size calculation.

Results: The cohort consisted of 529 subjects invasively ventilated for more than 24 h and extubated after successful 1-hour T-piece SBT ($n = 303$, 57%) or 1-h PS0 ZEEP SBT ($n = 226$, 43%). The reintubation rate at day 7 was 14.6% with PS0 ZEEP and 17.5% with T-piece (difference -2.6% [95% confidence interval, -8.3% to 4.3%]; $p = 0.40$). The reasons for reintubation did not differ significantly when compared between patients with 1-h PS0 ZEEP SBT and patients with 1-hour T-piece SBT.

Conclusion: Our results suggest that successful 1-hour T-piece and 1-h PS0 ZEEP SBTs are associated with similar reintubation rates at day 7.

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1. Introduction

Avoiding unnecessary extension of mechanical ventilation (MV) durations without exposing patients to an increased risk of extubation failure is a daily concern in the intensive care unit (ICU). In practice, MV weaning parameters are first assessed by clinicians, and then the weaning test is decided [1]. In subjects invasively ventilated for more than 24–48 h, it is recommended to test their ability to breathe with no assistance or with a minimal level of assistance before extubation [2,3]. A standard test for extubation readiness is the spontaneous breathing trial (SBT). The SBT can be more or less effort demanding depending on its duration (typically between 30 min and 2 h [4,5]) and whether it is conducted without (i.e., T-piece SBT) or with low levels of pressure support (PS) ventilation (i.e., PS SBT) [6]. In the T-piece

SBT, the subject is disconnected from the ventilator, and additional oxygen is provided without positive pressure. The PS SBT is generally conducted with a low level of PS and performed without disconnecting the patient from the ventilator. Low levels of PS are typically applied during the PS SBT to compensate for the imposed workload due to the ventilator circuit. So far, the standard is a SBT with 8 cmH₂O PS ventilation with or without PEEP. However, the work imposed by the ventilator circuit has been considerably reduced with technological improvements [7]. The aim of using a 1-h PS0 ZEEP SBT more than a 1-hour T-piece SBT is not to hasten extubation but to take potential advantages associated with maintaining the connection between the patient and ventilator. First, adequate humidification is ensured throughout SBT, and alarms for expiratory volume and respiratory breath are activated. Second, expiratory volume can be monitored, allowing calculation of minute ventilation and ratio of respiratory breath on expiratory volume, and these features are not available with the T-piece procedure. Third, the mode of ventilation used prior to extubation can be easily and quickly reintroduced in patients who fail SBTs, especially in those with severe signs of respiratory or haemodynamic poor tolerance. Fourth, there is

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less handling of the ventilator tubing and less risk of aerosols when disconnecting, especially in patients with pulmonary infection. Following a physiologic meta-analysis, Michael C Sklar et al. [8] concluded that T-piece SBT and PS of 0 cm H₂O (PS0) SBT both accurately reflect physiologic conditions of extubation. One-hour T-piece SBT or 1-h PS0 with zero end expiratory pressure (ZEEP) SBT are both used in our ICU to test subjects before extubation depending on the physician in charge of the subject. Despite published recommendations, MV weaning practices vary between teams [9], and we suspect that maintaining the patient connected to the ventilator with a low trigger and PS0 ZEEP during SBT could be a widespread practice that, to the best of our knowledge, has not been previously assessed in a large population. To evaluate our practices and to confirm the hypothesis that extubation failure rates are similar whether extubation is performed following T-piece or PS0 ZEEP SBT, we performed a prospective observational study.

2. Patients and methods

2.1. Patients

The study was approved by the hospital's ethics committee (number 18–24). Subjects intubated for more than 24 h, without do not reintubate order and tested for extubation with SBT were screened for the study. In our 24-bed ICU of a tertiary teaching hospital, the duration of the SBT is planned for 1 h in all subjects and stopped earlier when poorly tolerated. Two ventilators were available during the study period: Evita XL (Dräger) and Servo I (Getinge). The 1-hour T-piece or 1-h PS0 ZEEP SBT was decided by the physician in charge. During SBT, respiratory and heart rates, pulse oximetry (SpO₂), arterial blood pressure, and transcutaneous PCO₂ (PtcCO₂) (TCM5, Radiometer, Copenhagen, Denmark) were monitored and recorded at 0, 15, 30, 45, and 60 min after the start of the SBT. Subjects were also monitored for signs of poor respiratory and haemodynamic tolerance. In accordance with previous studies, the following criteria are used in our ICU to define SBT failure: development during the SBT of any of the following events including respiratory rate > 35 breaths/min, increased accessory muscle activity, SpO₂ persistently less than 90% despite increasing FiO₂, heart rate persistently greater than 140 beats/min, systolic blood pressure < 90 or > 180 mmHg, appearance of cyanosis or mottling, depressed mental status or agitation [2,3,10,11].

Extubations were performed with the assistance of a nurse and a physiotherapist under the physician's control. Patients were identified ready to undergo an SBT and to have failed SBT using criteria from the international conference consensus on weaning [10].

2.2. Data collection

In addition to the variables monitored during SBT, based on recent literature [2,3,11–14], the following data were prospectively recorded: baseline characteristics of subjects at admission, including simplified acute physiology score (SAPS) II [15], moderate to severe acute respiratory distress syndrome (ARDS) [16], risk factors for extubation failure [3,12,17], the main reason for intubation, and weaning difficulty. Subjects were distinguished by whether they were extubated within 24 h after the first SBT (defined as simple weaning), extubated more than 24 h and less than 7 days after the first unsuccessful SBT (defined as difficult weaning), and extubated more than 7 days after the first unsuccessful SBT (defined as prolonged weaning) [10]. Subjects were classified for weaning difficulty independently of the issue of extubation and based exclusively on the fact that the patient was extubated or not. At the time of extubation, the following data were recorded: body mass index, sequential organ failure assessment (SOFA) scores [18], previous duration of MV, number of previous SBTs without extubation, ventilator settings, quality of cough strength and amount of secretions assessed by nurses [19]. Variables recorded after extubation included the following: treatment with noninvasive ventilation (NIV) and high-

flow oxygen therapy (HFOT), time and reason for reintubation, length of ICU stay, and ICU and hospital mortality. Extubation failure was defined as a need for reintubation within the 7 days following extubation. The main reasons for intubation, risk factors for extubation failure, underlying chronic respiratory diseases, underlying cardiac diseases, obesity, weaning groups, the amount of secretions scoring and quality of cough, and reason for reintubation are defined in the supplemental material. All subjects in the study were assessed for the first extubation during the ICU stay.

2.3. Sample size calculation and statistical analysis

To avoid a lack of power, we used a non-inferior approach for the sample size calculation. First, and although we did not perform a randomized controlled study, the minimum number of subjects needed in each group was calculated based on the hypothesis that 1-h PS0 ZEEP SBP was non-inferior to 1-hour T-piece SBP for extubation failure at day 7. In a prospective randomized study, a minimum of 219 subjects per group should have been included to provide a power of 90% rather than 80% to establish non-inferiority to T-piece SBT using a 15% reintubation rate at day 7, a 10% non-inferiority margin, and a 2-sided α level of 0.05 [20]. Data are expressed as numbers and percentages and as medians and interquartile ranges (IQRs). The chi-square test was used to compare categorical variables, and the Mann-Whitney *U* test was used to compare continuous variables. Second, we expressed differences in clinical outcomes (SBT and reasons for reintubation) using the absolute difference with 95% confidence intervals (Cis). Third, Kaplan-Meier curves were constructed for freedom from reintubation at day 7 and compared by log rank test. Deaths occurring before day 7 were introduced in the survival analysis as censored data. In addition, a multiple logistic regression analysis was performed for extubation failure or success at day 7 to adjust on 1-hour T-piece SBT and on variables achieving a *p*-value < 0.05 in the unadjusted analysis after comparison between patients who failed and patients who succeeded extubation at day 7. The results are presented as odds ratios (ORs) with 95% Cis with continuity correction. Repeated measures were compared with the use of two-way analysis of variance (ANOVA). A two-tailed *p* < 0.05 was considered to indicate statistical significance. Statistical analyses were performed using the Statistical Package for Social Sciences 25 (SPSS, IBM., Chicago, IL, USA).

3. Results

3.1. Patients

From February 1, 2018 to December 12, 2020, 895 patients received more than 24 h of MV, among whom 623 patients (69%) were screened for the study because they performed at least one SBT. Of note, 38 subjects (6%) were excluded from the study because they had PS8 ZEEP SBT after inclusion in the Tip-Ex study [21]. Five hundred and twenty-nine subjects with no missing data were observed, and their data were analysed. Among the 529 subjects, 303 subjects (57%) underwent 1-hour T-piece SBT, and 226 subjects (43%) underwent 1-h PS0 ZEEP SBT before being extubated (Fig. 1). The characteristics of subjects before extubation, day of extubation, and NIV received after extubation were compared to determine whether subjects underwent 1-hour T-piece SBT or 1-h PS0 ZEEP SBT before extubation, and the results are listed in Table 1. Among the 83 postoperative subjects, 50 patients (60%) were liver transplant recipients, and 13 patients (16%) underwent cardiac surgery. Subject characteristics did not differ between the two groups of subjects (Table 1).

3.2. Primary outcome

The reintubation rate at day 7 after extubation was 17.5% (95% CI, 13.2%–21.8%) with a 1-hour T-piece SBT and 14.6% (95% CI, 10.0%–

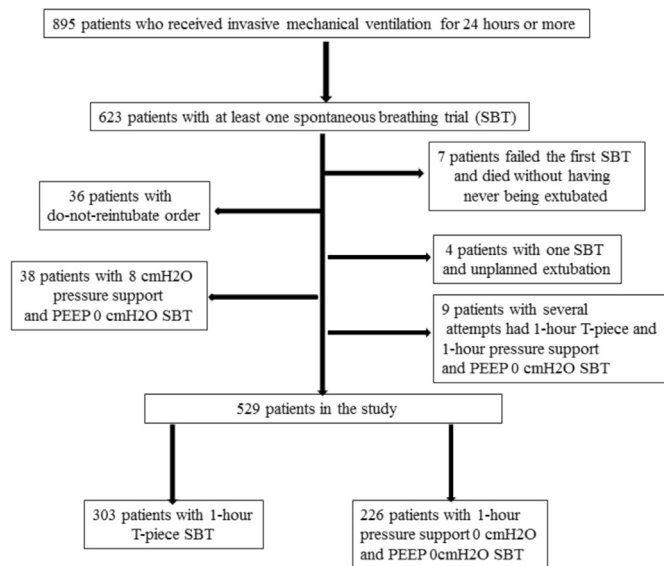


Fig. 1. Flow chart of subjects.

19.2%) with a 1-h PSO ZEEP SBT (difference, -2.6% ; 95% CI, -8.3% to 4.3% , $p = 0.40$) (Table 2). After adjustment on ventilator settings before SBT and absent or weak cough, the OR of 1-hour T-piece SBT for reintubation at day 7 was 1.02 (95% CI, 0.24–4.29, $p = 0.97$). The Kaplan–Meier curve constructed from time to extubation until day 7 after extubation showed no significant difference in freedom from reintubation between the two SBT methods (Fig. 2).

3.3. Secondary outcomes

We found no significant difference when the two methods of SBT were compared for reintubation rates at 48 h, reintubation or death rates at day 7, number of SBT attempts before extubation, and delays between first SBT and extubation (Table 2).

3.4. Exploratory outcomes

Length of stay in the ICU, ICU and hospital mortality rates did not differ significantly whether subjects were extubated after 1-hour T-piece SBT or 1-h PSO ZEEP SBT (Table 2). In addition, reasons for reintubation did not differ between the two different types of SBTs (Table 3).

Repeated values of heart rate, systolic arterial pressure, and PtcCO₂ did not differ significantly whether SBT was performed with a T-piece or PSO ZEEP (Supplemental Fig. 1). Respiratory rate and SpO₂ values were significantly increased in subjects patients with PSO ZEEP compared with subjects with a T-Piece with a mean difference of 1.8 breaths rate per minute and of 2% respectively ($p < 0.001$).

3.5. Additional and subgroup analyses

Among the 267 subjects who were reconnected and ventilated at least one hour before extubation, the rate of reintubation at day 7 did not differ significantly between subjects with a 1-hour T-piece SBT (29 of 147 subjects, 20%) and patients with a 1-h PSO ZEEP (22 of 120 subjects, 18%) ($p = 0.77$ after comparison). Similarly, the rates of reintubation at day 7 did not differ significantly between 1-hour T-piece subjects and 1-h PSO ZEEP subjects in the subgroup of subjects who received prophylactic NIV (19% vs 17%, respectively, $p = 0.75$). In addition, when a comparison was performed on the subgroup of 266 subjects who were ventilated for more than 48 h, reintubation rates at day 7 after extubation did not significantly differ between the 1-hour

Table 1
Baseline characteristics of the patients.

Variable	1-hour T-piece SBP	1-h PSO ZEEP SBP	P value
	n = 303	n = 226	
Age, median (IQR), years	62 (54–70)	60 (53–68)	0.22
Sex, n (%)			0.39
Men	212 (69.9)	150 (66.3)	
Women	91 (30.1)	76 (33.7)	
SAPS II score at admission, median (IQR)	51 (36–64)	47 (37–58)	0.22
Respirator, n (%)			0.52
Evita XL Dragger	182 (60.1)	142 (62.8)	
Servo I Maquet	121 (39.9)	84 (37.2)	
Size of endotracheal tube			0.16
7	105 (34.7)	93 (41.1)	
7.5	155 (51.1)	97 (42.9)	
Other than 7 or 7.5	43 (14.2)	36 (15.9)	
Main reason for intubation, n (%)			0.26
Surgery	46 (15.2)	37 (16.4)	
Acute respiratory failure	102 (33.6)	96 (42.4)	
Acute on chronic respiratory failure	32 (10.6)	20 (8.3)	
Cardiac arrest	16 (5.3)	9 (3.5)	
Shock	33 (10.9)	25 (11.1)	
Central nervous system disorder	62 (20.5)	37 (16.3)	
Other	12 (3.9)	2 (2.0)	
Obesity, n (%)	101 (32.7)	61 (26.1)	0.12
ARDS, n (%)	47 (15.5)	49 (21.6)	0.068
Weaning difficulty			0.16
Simple	180 (59.4)	131 (57.9)	
Difficult	89 (29.4)	79 (34.9)	
Prolonged	34 (11.2)	16 (7.2)	
Risk factor of extubation failure, n (%)			
Age > 65 years	115 (37.9)	75 (33.1)	0.26
MV duration > 7 days, n (%)	164 (54.1)	113 (50.0)	0.35
Underlying chronic cardiac disease, n (%)	97 (32.0)	78 (34.5)	0.55
Underlying chronic respiratory disease, n (%)	109 (35.9)	79 (34.9)	0.81
Previous neurological disorder, n (%)	69 (22.7)	45 (19.9)	0.42
Duration of MV before extubation, median (IQR), days	8 (5–14)	7 (4–15)	0.68
BMI the day of extubation, median (IQR), kg/m ²	26 (23–31)	26 (22–29)	0.065
SOFA score the day of extubation, median (IQR), point	4 (2–5)	4(2–5)	0.97
Ventilator settings before SBT			0.03
PS ventilation	215 (70.9)	140 (61.9)	
Assist-control ventilation	88 (29.0)	86 (38.0)	
PaO ₂ /FiO ₂ before SBT, median (IQR) mmHg	283 (220–362)	280 (228–342)	0.43
PaCO ₂ before SBT, median (IQR) mmHg	39 (34–43)	39 (35–46)	0.18
Absent or weak cough, n (%)	94 (34)	51 (22)	0.039
Abundant or very abundant secretions, n (%)	104 (35)	87 (41)	0.38
Reconnection to ventilator and at-least 1-h of PS or assist-control ventilation before extubation	147 (48.5)	120 (53.1)	0.30
Non invasive ventilation after extubation			0.83
None	177 (58.4)	137 (60.6)	
Prophylactic immediately after extubation	107 (35.3)	77 (34.1)	
Not prophylactic to treat respiratory worsening	19 (6.3)	12 (5.3)	
Prophylactic high-flow nasal canula after extubation	22 (7.2)	21 (9.3)	0.54

SBT, spontaneous breathing trial; PS, pressure support; PEEP, positive end expiratory pressure; IQR, interquartile range; ARDS, acute respiratory distress syndrome; MV, mechanical ventilation; BMI, body mass index; SOFA, sepsis failure organ assessment.

T-piece SBT (19%) and 1-h PSO ZEEP (16%) ($p = 0.43$). Survival-free days of reintubation from the date of the first SBT to day 7 after extubation did not significantly differ between the two types of SBTs ($p = 0.22$ by the log-rank test).

Table 2
Primary, secondary, and exploratory outcomes.

Primary, secondary and exploratory outcomes	1-h PS = 0 PEEP = 0 SBP n = 226	1-hour T-piece SBP n = 303	Absolute Difference, (95% CI)	P value
Primary outcome				
Reintubation at day 7, n (%)	33 (14.6)	53 (17.5)	−2.6 (−8.3 to 4.3)	0.40
Secondary outcomes				
Reintubation at 48 h, n (%)	22 (9.7)	42 (13.8)	−4.5 (−9.6 to 1.6)	0.15
Reintubation or death at day 7, n (%)	35 (15.4)	56 (18.4)	−3.6 (−9.4 to 3.4)	0.43
Extubation after the first SBT, n (%)	146 (64.6)	207 (68.3)	−3.8 (−1.1 to 5.1)	0.48
Delay between the first attempt of SBP and extubation, median (IQR), hours	0 (0–24)	0 (0–24)	−7.5 (−24.7 to 23.6)	0.49
Exploratory outcomes				
Length of stay in the ICU, median (IQR)	11 (6–21)	10 (6–20)	0.4 (−2.1 to 2.9)	0.82
Mortality in ICU, n (%)	14 (6.2)	21 (6.9)	−0.008 (−0.05 to 0.03)	0.71
Mortality in hospital, n (%)	33 (14.6)	48 (15.8)	−1.6 (−7.5 to 5.2)	0.71

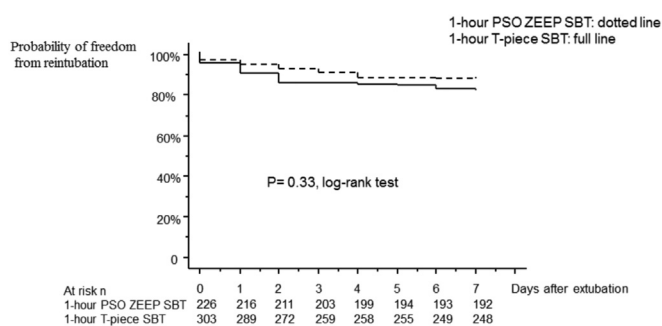


Fig. 2. Probability of freedom from reintubation after the first spontaneous breathing trial in each group.

4. Discussion

As hypothesized, we found that reintubation rates at day 7 did not differ significantly whether subjects were extubated after successful 1-hour T-piece SBT or successful 1-h PSO ZEEP SBT. In addition, reintubation rates at 48 h, reintubation or death rates at day 7, and proportions of patients extubated after the first attempt of SBT did not differ significantly after comparison between the 1-hour T-piece SBT and 1-h PSO ZEEP.

For the whole population, the rate of reintubation at day 7 was 16.2%, which is in the range of the 10 to 20% rate generally reported in studies [11,12,17,22,23]. In addition, this rate was very close to the 15% used for the sample size calculation. The baseline characteristics of subjects were similar to those reported in recent [11–13] and older [4] studies focusing on weaning from MV and the periextubation period. Similar to that reported in previous recent studies [11,12], a high percentage of our patients had a successful initial SBT followed by successful extubation at day 7. On the other hand, the proportion of subjects who received prophylactic high-flow nasal oxygen therapy (HFNOT)

after extubation was lower than that in the study of C. Subirà et al. [12] and than that in the study of AW. Thille et al. [11]. Less than 10% of the patients received HFNOT because this therapy was not recommended as a systematic treatment in patients at highest risk of reintubation during the study period. In addition, HFNOT was not available with Servo I ventilators.

As we reported, all subjects with risk factors for reintubation did not receive prophylactic NIV. Prophylactic NIV was first used mainly in patients with chronic obstructive pulmonary disease and second extended to patients with underlying chronic cardiac disease according to the HIGH-WEAN study [21]. Moreover, prophylactic NIV was not systematically applied in patients older than 65 years without respiratory or cardiac diseases but left at the discretion of physician in charge. Along these lines, the systematic 1-h reconnection period with prior ventilator settings after a successful SBT and before extubation was implemented during the study period when data from Fernandez et al. were published [24]. Although these two studies induced significant changes in our weaning practices, we did not find a significant difference in the frequency of reintubation regardless of whether the subjects received NIV after extubation or were reconnected after successful SBT.

The authors reported that in morbidly obese patients, a T-piece trial and the test performed without disconnecting the subjects with no PS ventilation and no PEEP predicted post-extubation work of breathing better than tests realized with PS ventilation and/or PEEP with similar accuracy [25]. In a physiologic meta-analysis assessing and comparing respiratory effort during T-piece SBT with various modalities of PS ventilation, the authors concluded the equivalence of T-piece and PSO trials [8]. Indeed, the “physiological” rationale existed to consider that evaluation of extubation readiness and success by 1-hour T-piece SBT and 1-h PSO ZEEP SBT could provide similar results. However, to our knowledge, this comparison has not been previously realized during a clinical study. The results of repeated respiratory and cardiac parameters recorded and compared between the two types of SBTs suggest that one is not more effort-demanding than the other.

Our study has several limitations. First, it was conducted at a single site; thus, the results may not be applicable to other ICUs. Second, the

Table 3
Reasons for reintubation.

Reason for reintubation, n (%)	1-hour T-piece SBP n = 50	1-h PS = 0 PEEP = 0 SBP n = 33	Absolute Difference, (95% CI)	P value
Excessive work of breathing	12 (24.0)	12 (36.3)	−12.3 (−31.9 to 7.2)	0.27
Difficulty in managing secretions	10 (20)	4 (12)	7.9 (−11.6–24.2)	0.17
Refractory hypoxemia	9 (18.0)	3 (9.0)	8.9 (−9.7 to 24.3)	0.12
Level of consciousness	5 (10)	2 (6.1)	3.9 (−12.8 to 17.5)	0.26
Airway obstruction	6 (12.0)	2 (6.1)	5.9 (−11.1 to 19.8)	0.18
Surgery	1 (2.0)	2 (6.0)	−4.0 (−7.1 to 1.9)	0.16
Cardiac arrest	3 (6.0)	2 (6.1)	−0.1 (−16.2 to 12.5)	0.49
Aspiration	1 (2.0)	1 (3.0)	−1.0 (−5.7 to 7.2)	0.38
Shock	3 (6.0)	2 (6.1)	−0.1 (−10.3 to 10.5)	0.49

investigator who recorded data (AG) was not blinded to the type of SBT and issue of extubation. Nevertheless, this did not modify the decision of reintubation by the physician in charge of the subject. Third, given the observational nature of the study, we cannot exclude uncontrolled confounders. However, reintubation rates did not differ significantly whether subjects were extubated after successful T-piece or PSO ZEEP SBTs, and it seems unlikely that an unmeasured risk factor for extubation failure may have resulted in statistically significant differences in reintubation rates after being taken into account in the analyses. Proportions of patients with chronic underlying respiratory and/or cardiac diseases did not differ between the two groups of patients. However, we cannot exclude other possible bias of using each technique, including nurses and physicians experience. The highest proportion of patients with absent or weak cough in the 1-hour T-piece SBT suggests that in some cases, the quality of the cough and/or mucus plugging may have influenced the choice of the SBT. The use of prophylactic NIV and reconnection to ventilators were implemented during the study period, but with the same rhythm for the two SBT practices studied here. The expected advantages of the PS ventilation were not observed, mainly because only patients who succeeded SBT were assessed for reintubation. Data regarding reasons for SBT failure were not recorded and consequently could not be compared between the two groups of patients. Aerosol-generating tubing disconnection was beyond the scope of the study.

5. Conclusion

Using a non-inferiority approach, 1-hour T-piece SBT was compared to 1-h PSO zero PEEP SBT for reintubation at day 7 after extubation. In accordance with physiologically published data and as hypothesized, our results suggest that the ability to detect patients' readiness for extubation and reintubation rates within the week following extubation are similar whether a 1-h SBT is performed with a T-piece or PSO ZEEP. Compared to T-piece SBT, no subject disconnection from the ventilator could facilitate monitoring of SBT tolerance, may reduce the burden of care, and could prevent aerosols of pathogens.

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Declaration of Competing Interest

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jccr.2021.10.016>.

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