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Evaluation of an Automated Endotracheal Tube Cuff Controller During Simulated Mechanical Ventilation

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BACKGROUND: Maintaining endotracheal tube cuff pressure within a narrow range is an important factor in patient care. The goal of this study was to evaluate the IntelliCuff against the manual technique for maintaining cuff pressure during simulated mechanical ventilation with and without movement. METHODS: The IntelliCuff was compared to the manual technique of a manometer and syringe. Two independent studies were performed during mechanical ventilation: part 1, a 2-h trial incorporating continuous mannikin head movement; and part 2, an 8-h trial using a stationary trachea model. We set cuff pressure to 25 cm H_2O, PEEP to 10 cm H_2O, and peak inspiratory pressures to 20, 30, and 40 cm H_2O. Clinical importance was defined as both statistically significant ($P < .05$) and clinically significant (pressure change [Δ] > 10%). RESULTS: In part 1, the change in cuff pressure from before to after ventilation was clinically important for the manual technique ($P < .001$, $\Delta = -39.6\%$) but not for the IntelliCuff ($P = .02$, $\Delta = 3.5\%$). In part 2, the change in cuff pressure from before to after ventilation was clinically important for the manual technique ($P = .004$, $\Delta = -14.39\%$) but not for the IntelliCuff ($P = .20$, $\Delta = 5.65\%$). CONCLUSIONS: There was a clinically important drop in manually set cuff pressure during simulated mechanical ventilation in a stationary model and an even larger drop with movement, but this was significantly reduced by the IntelliCuff in both scenarios. Additionally, we observed that cuff pressure varied directly with inspiratory airway pressure for both techniques, leading to elevated average cuff pressures. *Key words: IntelliCuff; endotracheal tube; ETT cuff; cuff pressure; mechanical ventilation; cuff pressure controller.* [Respir Care 2015;0(0):1–•. © 2015 Daedalus Enterprises]

Introduction

The proper maintenance of endotracheal tube (ETT) cuff pressure during mechanical ventilation is increasingly recognized as an important factor in patient care. It is generally accepted that optimal patient treatment includes keeping cuff pressure within a narrow range (20–30 cm H_2O).[1-8] Cuff pressures above this range can occlude perfusion of tracheal mucosa, which can lead over time to significant tissue ischemia.[1-5] In contrast, cuff pressures below 20 cm H_2O may create an incomplete seal, which can cause air leak around the cuff, disrupting ventilation, and allow contaminated oral secretions to be microaspirated into the lower airway,[6-8] a primary cause of ventilator-associated pneumonia.[9,10] Ventilator-associated pneumonia is a problematic complication of mechanical ventila-

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tion and is associated with significant morbidity, mortality, and cost.[11]

Striking the necessary balance between underinflation and overinflation requires rigorous cuff management.[12] In response to this need, various devices have been manufactured to automatically and continuously control cuff pressures, and several were shown to more successfully maintain ETT cuff pressure compared to the standard practice of manually measuring and adjusting cuff pressure with a manometer and syringe.[13-17] Nonetheless, these devices have not seen widespread implementation in the clinical setting. Most are free-standing devices, independent from the ventilator itself. Hamilton Medical (Reno, Nevada) is the first to incorporate such a system, the IntelliCuff, into their G5 ventilator, although its function has not yet been evaluated.

Additionally, a recent study by Lizy et al[18] demonstrated that simple and commonly used changes in patient positioning often lead to significant and dangerous changes in cuff pressure. Continuous cuff pressure controllers have not been evaluated for their ability to maintain cuff pressure in the setting of patient movement.

The goal of this study was to evaluate the IntelliCuff against the current standard practice during simulated mechanical ventilation with and without patient movement. Our hypothesis was that the IntelliCuff would outperform the manual technique in maintaining a constant pressure in all scenarios.

QUICK LOOK

Current knowledge

Monitoring endotracheal tube (ETT) cuff pressure is a routine practice to prevent microaspiration and mucosal damage. Maintaining ETT cuff pressure within a narrow range in routine practice is complicated by positive-pressure ventilation, patient movement, and time.

What this paper contributes to our knowledge

In a bench model of endotracheal intubation and mechanical ventilation, manually set cuff pressures frequently descended below the therapeutic range. This was prevented by use of an automated cuff pressure controller. With both techniques, cuff pressure varied directly with inspiratory airway pressure, leading to elevated average cuff pressures.

Methods

Comparison of the 2 cuff inflation techniques (manual and IntelliCuff) was performed in 2 independent bench studies: part 1, a 2-h trial incorporating continuous mannikin head movement; and part 2, an 8-h trial using a stationary trachea model.

Part 1: 2-h Trial With Head Movement

The setup for part 1 is shown in Figure 1. An anatomically correct mannikin head (Laerdal Airway Management Trainer, Laerdal, Wappingers Falls, New York) was altered to allow for computer-controlled 3-dimensional movement and attached to a test lung (Michigan Instruments, Grand Rapids, Michigan), set at a resistance of 5 cm H_2O/L/s and compliance of 0.05 L/cm H_2O. The mannikin was intubated with an 8.0-mm internal diameter ETT (Hi-Lo oral/nasal tracheal tube cuffed, Mallinckrodt, Hazelwood, Missouri), which uses a standard polyvinyl chloride high-volume low-pressure cuff design and was attached to a G5 ventilator with IntelliCuff.

The ETT pilot balloon was connected to a 3-way stopcock, with one outlet connected to a pressure transducer that was then connected to an analog-digital converter (DataQ Logger, model DI-718B-U, DATAQ Instruments, Akron, Ohio) that continuously logged pressure values in data acquisition software (WinDaq, DATAQ Instruments) at 120 Hz. The other outlet was used to measure and adjust cuff pressure by connecting a syringe or the IntelliCuff port.

Before ventilation, the ETT cuff was inflated to 25 cm H_2O manually or set with the IntelliCuff. The mannikin was then ventilated on pressure control mode at a breathing frequency of 20 breaths/min and an inspiratory-expiratory ratio of 1:2 with PEEP of 10 cm H_2O and total peak inspiratory pressures (PIP) of 20, 30, and 40 cm H_2O.

At the start of ventilation, mannikin head movement was initiated, continuously generating simultaneous vertical and lateral movement, as depicted in Figure 1. The vertical movement went from a neutral position to an elevation of 25° and back to neutral over a period of 1.2 s (average of 0.73 rad/s). The lateral movement made an arc from 20° left to 20° right and back over a period of 2.0 s (average of 0.70 rad/s).

Run duration was 2 h with each of 5 new ETTs, which were verified to be leak-free by submersion in water before use. Each ETT was used for one manual and one IntelliCuff run at each PIP in random order.

Part 2: 8-h Stationary Trial

A trachea model, as described by Pitts et al,[19] consisting of silicon tubing (28-cm length and 2.3-cm internal diameter) was used for this study. The trachea model was lightly clamped in a stationary vertical position, intubated without lubrication, and connected to a test lung. The test lung, ventilator, and 3-way stopcock system were as described for part 1.

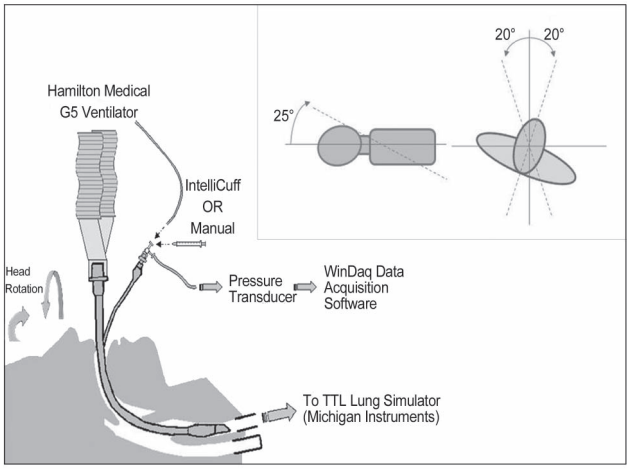

Fig. 1. Part 1 setup for simulated patient movement. A Laerdal Airway Management Trainer was altered by removing the head and neck from the torso and fixing it to a computer-controlled platform to allow movement on 2 planes (inset), and configured as shown. The vertical movement finished a complete cycle in 1.2 s; the lateral movement completed a cycle in 2.0 s. TTL = Training and Test Lung.

Run duration was 8 h. Data were collected for both techniques with cuff pressure of 25 cm H_2O, PEEP of 10 cm H_2O, and PIP of 20, 30, and 40 cm H_2O ($n = 3$). A new 8.0-mm inner diameter Hi-Lo ETT was used for this part of the study and was verified to be leak-free by submersion in water before use.

Data Collection and Analysis

In both parts of the study, cuff pressure was continuously recorded and analyzed for the percentage of time within the optimal pressure range of 20–30 cm H_2O. This was done by collapsing the data into 3-s averages. Additionally, 5 points in time (1. after setting the cuff but before ventilation [start]; 2. the first 5 ventilated breaths; 3. the middle 5 ventilated breaths; 4. the last 5 ventilated breaths; and 5. after the ventilator was disconnected [end]) were analyzed in more detail to detect changes in pressure over time and the differences between peak (the highest cuff pressure during each ventilatory cycle) and baseline (the lowest cuff pressure during each ventilatory cycle) cuff pressures.

Statistical analysis was performed with commercially available SAS-based software (JMP, Cary, North Carolina) using paired-sample *t* tests. A difference was considered to be clinically important if it was both statistically significant ($P < .05$) and clinically significant (pressure change [Δ] > 10%).

Results

Part 1: 2-h Trial With Head Movement

The results of the simulated movement component of the study, broken down into peak and baseline cuff pressures and compiled across all 3 PIP settings, are shown in Figure 2. The average start cuff pressure for the manual technique was 25.11 ± 0.30 cm H_2O, and the average end cuff pressure was 15.16 ± 8.53 cm H_2O, an average pressure change of −9.95 cm H_2O. For the IntelliCuff, these values were 25.59 ± 0.83 and 26.51 ± 0.28 cm H_2O, respectively, an average change of 0.92 cm H_2O. These changes were clinically important for the manual technique ($P < .001$, $\Delta = -39.6\%$) but not for the IntelliCuff ($P = .02$, $\Delta = 3.5\%$).

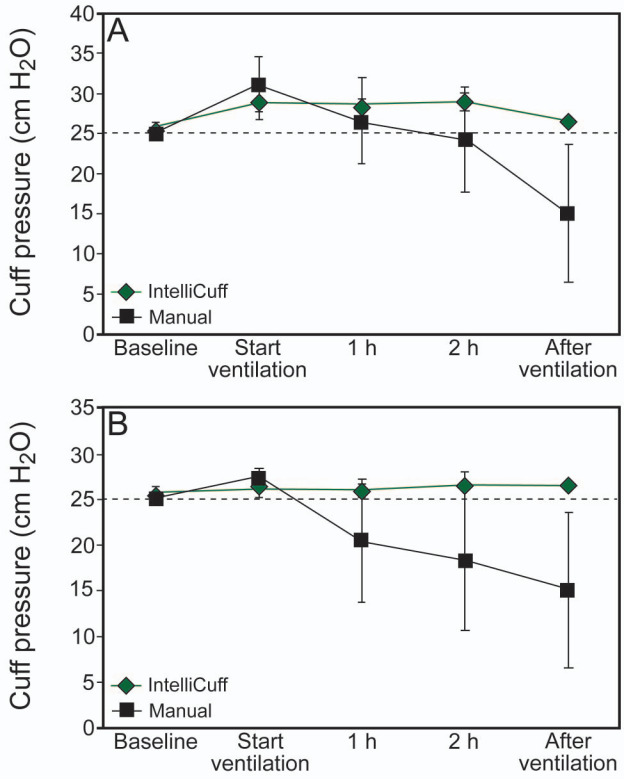

Fig. 2. Graphs of peak (A) and baseline (B) cuff pressures at 5 points in time during 2 h of ventilation with movement for the IntelliCuff and manual techniques. The 5 points represent cuff pressures before ventilation, during the first 5, middle 5, and last 5 breaths of ventilation (at initiation, 1 h, and 2 h, respectively), and after ventilation was stopped. Peak and baseline cuff pressures represent the highest and lowest points during each respiratory cycle. Each data point is the average of 5 endotracheal tubes, each tested at peak inspiratory pressures of 20, 30, and 40 cm H_2O ($n = 15$). Error bars are SD. The cuff pressure was set to 25 cm H_2O before the initiation of ventilation in all scenarios, as shown by the dashed lines.

Table 1 shows the percentage of time that cuff pressure, collapsed into 3-s averages, was within the acceptable range for each technique overall and broken down by PIP. For the IntelliCuff, overall cuff pressure was between 20 and 30 cm H_2O for 94.7% of the time, with 5.3% above 30 cm H_2O and 0.0% below 20 cm H_2O. For the manual technique, overall cuff pressure was between 20 and 30 cm H_2O for 71.6% of the time, with 6.9% above

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Table 1. Percentage of Time Within the Acceptable Cuff Pressure Range Across 3 PIP Settings and Overall for Both the IntelliCuff and Manual Technique During 2 h of Ventilation With Movement

	PIP 20 cm H_2O			PIP 30 cm H_2O			PIP 40 cm H_2O			All PIP		
	IntelliCuff	Manual	*P*	IntelliCuff	Manual	*P*	IntelliCuff	Manual	*P*	IntelliCuff	Manual	*P*
% at > 30 cm H_2O*	0.033 ± 0.07	0.04 ± 0.09	.45	0.84 ± 0.70	0.09 ± 0.20	.05	15.15 ± 25.87	20.47 ± 44.44	.28	5.34 ± 15.59	6.87 ± 25.76	.29
% at 20–30 cm H_2O†	99.97 ± 0.07	82.91 ± 38.04	.19	96.16 ± 0.70	81.37 ± 38.96	.18	84.85 ± 25.87	50.52 ± 46.17	.06	94.66 ± 15.59	71.59 ± 41.16	.01
% at < 20 cm H_2O‡	0.00 ± 0.00	17.05 ± 38.06	.19	0.00 ± 0.00	18.53 ± 39.01	.17	0.00 ± 0.00	29.01 ± 39.76	.09	0.00 ± 0.00	21.54 ± 36.48	.02

All data are mean ± SD for 5 different endotracheal tubes.
* Percentage of time that the cuff pressure was above 30 cm H_2O
† Percentage of time that the cuff pressure was between 20 and 30 cm H_2O
‡ Percentage of time that the cuff pressure was below 20 cm H_2O
PIP = peak inspiratory pressure

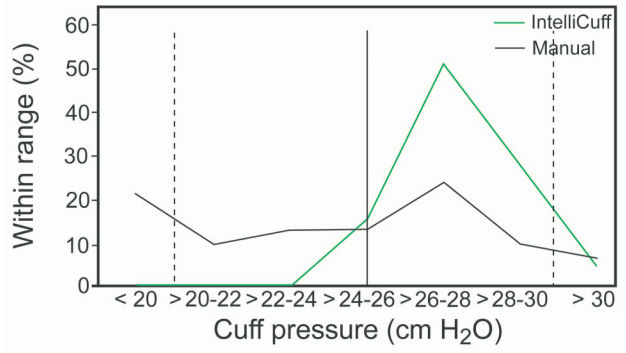

Fig. 3. Percentage of total time cuff pressure recordings were within each range during 2 h of ventilation with movement for both the IntelliCuff and manual technique. Each recording corresponds to the average cuff pressure during 3 s of ventilation. A higher curve denotes a higher frequency of cuff pressure observations within that range. The total number of observations is the same for the 2 techniques and includes all tested scenarios in the first part of the study. The initial set cuff pressure was 25 cm H_2O, as shown by the solid vertical line in the middle. The outer dashed lines depict the edges of the generally accepted cuff pressure range of 20–30 cm H_2O.

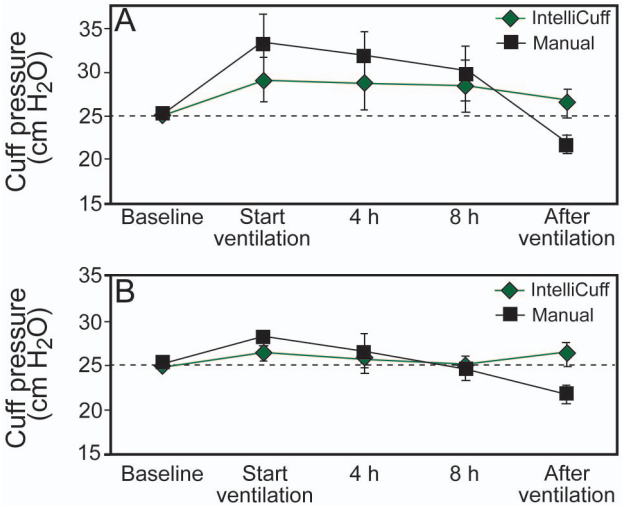

Fig. 4. Graphs of peak (A) and baseline (B) cuff pressure at 5 points in time during 8 h of ventilation without movement for the IntelliCuff and manual techniques. The 5 points represent cuff pressures before ventilation, during the first 5, middle 5, and last 5 breaths of ventilation (at initiation, 4 h, and 8 h, respectively), and after ventilation was stopped. Peak and baseline cuff pressures represent the highest and lowest points during each respiratory cycle. Each data point is the average of 5 endotracheal tubes, each tested at peak inspiratory pressures of 20, 30, and 40 cm H_2O (n = 15). The cuff pressure was set to 25 cm H_2O before the initiation of ventilation in all scenarios, as shown by the dashed lines. Error bars represent SD.

30 cm H_2O and 21.5% below 20 cm H_2O. Overall time spent in the acceptable range was significantly better for the IntelliCuff (P = .03).

When broken down by PIP, the IntelliCuff maintained cuff pressure within the acceptable range for a higher percentage of time at all 3 PIP settings, but these differences were not statistically significant. Both the IntelliCuff and manual technique performed notably worse at the highest PIP of 40 cm H_2O. Figure 3 shows graphically the percentage of time average cuff pressure was in specific ranges in all 2-h scenarios.

Part 2: 8-h Stationary Trial

The results of the long component of the study, broken down into peak and baseline cuff pressures and compiled across all 3 PIP settings, are shown in Figure 4. The average start cuff pressure for the manual technique was 25.31 ± 0.31 cm H_2O, and the average end cuff pressure was 21.67 ± 1.09 cm H_2O, giving an average pressure change of −3.64 cm H_2O. For the IntelliCuff, these values were 24.87 ± 0.30 and 26.28 ± 1.38 cm H_2O, respectively, giving an average change of 1.41 cm H_2O. This change was clinically important for the manual technique (P = .004, Δ = −14.39%) but not for the IntelliCuff (P = .20, Δ = 5.65%).

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Table 2. Percentage of Time Within the Acceptable Cuff Pressure Range Across 3 PIP Settings and Overall for Both the IntelliCuff and Manual Technique During 8 h of Ventilation Without Movement

	PIP 20 cm H_2O		PIP 30 cm H_2O		PIP 40 cm H_2O		All PIP		
	IntelliCuff	Manual	IntelliCuff	Manual	IntelliCuff	Manual	IntelliCuff	Manual	*P*
% at > 30 cm H_2O*	0.00	0.00	0.02	40.90	3.21	33.05	1.08 ± 1.84	24.65 ± 21.70	.10
% at 20–30 cm H_2O†	100.00	100.00	99.98	59.10	96.79	66.95	98.92 ± 1.84	75.35 ± 21.70	.10
% at < 20 cm H_2O‡	0.00	0.00	0.00	0.00	0.00	0.00	0.00 ± 0.00	0.00 ± 0.00	–

All data are mean ± SD of the individual PIP settings ($n = 3$). Because multiple runs were not performed, *P* values could not be calculated for individual PIP settings.
* Percentage of time that the cuff pressure was above 30 cm H_2O
† Percentage of time that the cuff pressure was between 20 and 30 cm H_2O
‡ Percentage of time that the cuff pressure was below 20 cm H_2O
PIP = peak inspiratory pressure

Table 2 shows the percentage of time that cuff pressure, collapsed into 3-s averages, was within the acceptable range for each technique overall and broken down by PIP during the long component. For the IntelliCuff, overall cuff pressure was between 20 and 30 cm H_2O for 98.9% of the time, with 1.1% above 30 cm H_2O and 0.0% below 20 cm H_2O. For the manual technique, overall cuff pressure was between 20 and 30 cm H_2O for 75.35% of the time, with 24.7% above 30 cm H_2O and 0.0% below 20 cm H_2O. These differences were not statistically significant.

When broken down by PIP, the IntelliCuff maintained cuff pressure within the acceptable range for a higher but statistically insignificant percentage of time at PIP of 30 and 40 cm H_2O, whereas both techniques performed equally well at PIP of 20 cm H_2O. Figure 5 shows graphically the percentage of time average cuff pressure was in specific ranges in all 8-h scenarios.

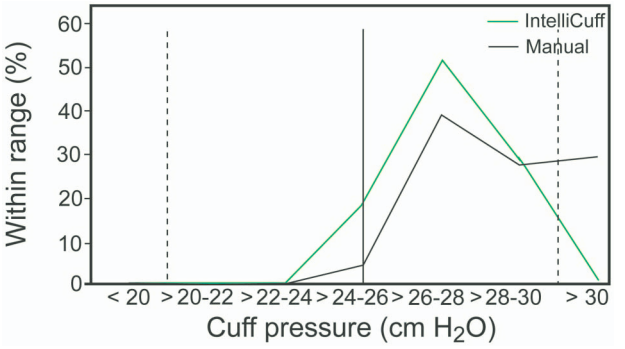

Fig. 5. This graph shows the percentage of total time cuff pressure recordings were within each range during 8 h of ventilation without movement for both the IntelliCuff and manual technique. Each recording corresponds to an average cuff pressure during 3 s of ventilation. A higher curve denotes a higher frequency of cuff pressure observations within that range. The total number of observations is the same for the 2 techniques and includes all tested scenarios in the second part of the study. The initial set cuff pressure was 25 cm H_2O, as shown by the solid vertical line in the middle. The outer dashed lines depict the edges of the generally accepted cuff pressure range of 20–30 cm H_2O.

Effect of PIP on Cuff Pressure

Figure 6 shows representative cuff pressure waveforms for the IntelliCuff and manual technique at PIP of 20 and 40 cm H_2O. A higher PIP resulted in a higher amplitude of the cuff pressure waveform, indicating a higher peak pressure. Additionally, the amplitude was higher when the cuff was set manually compared to the IntelliCuff at the same PIP setting.

Discussion

The main findings of this study can be summarized as: (1) with simulated patient movement, manually set cuff pressure dropped significantly within 2 h; (2) in a stationary model, manually set cuff pressure experienced a small but significant drop over 8 h but was more likely to be above the set pressure than below; (3) higher PIP was associated with higher average cuff pressures; and (4) the IntelliCuff was able to prevent low average cuff pressures and partially prevent high average pressures.

Several studies show that cuff pressure is routinely outside of this range in clinical practice and that cuff pressure tends to decrease over time.[5,20,21] Sridermma et al[22] found that cuff pressure decreased to 20 cm H_2O within 4–5 h after setting the cuff pressure to 25 cm H_2O, whereas Sole et al[12] found that significant drops occurred within the first hour. Our results demonstrate that clinically important drops out of the desired range frequently occur in < 2 h without intervention when significant patient movement occurs. In a stationary model, as might be seen in a sedated or paralyzed patient, the pressure decrease during 8 h of mechanical ventilation was small but clinically important.

In the stationary model, cuff pressure above the acceptable range was a more prevalent problem than pressure below the range. These high pressures are explainable by

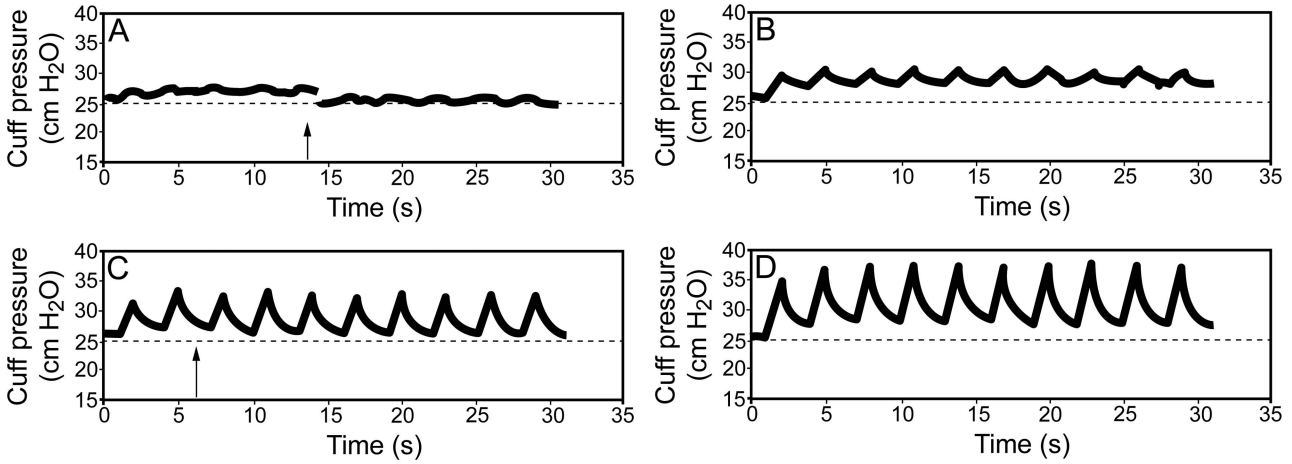

Fig. 6. Representative cuff pressure waveforms during the first 10 breaths of ventilation with the IntelliCuff or the manual technique at peak inspiratory pressure (PIP) of 20 or 40 cm H_2O. A: IntelliCuff with PIP of 20 cm H_2O. B: Manual technique with PIP of 20 cm H_2O. C: IntelliCuff with PIP of 40 cm H_2O. D: Manual technique with PIP of 40 cm H_2O. The cuff pressure was set to 25 cm H_2O before the initiation of ventilation in all scenarios, as shown by the dotted lines. The arrows in A and C indicate adjustments toward the set cuff pressure made by the IntelliCuff.

analysis of the cuff pressure waveforms during ventilation (see Fig. 6). Since cuff pressure was set before the initiation of ventilation, the positive pressure in the airway led to an increase in the baseline cuff pressure above the set pressure, and each respiratory cycle caused cyclic variation in the cuff pressure as the positive pressure in the airway increased and returned to the PEEP level. Because higher PIP settings led to higher peak cuff pressures (Fig. 6), average cuff pressures above the acceptable range occurred more frequently with higher PIP, as shown in Tables 1 and 2. The clinical importance of this cyclic variation in cuff pressure requires additional research.

Previous studies have demonstrated the ability of several devices to maintain cuff pressure,[13-17] and the IntelliCuff performed comparably in our study. Nseir et al[14] evaluated a pneumatic device (Nosten, Leved, Saint-Maur, France) in piglets intubated for 48 h and found that it effectively maintained cuff pressure compared to the manual technique. They defined the acceptable pressure range as 15–30 cm H_2O, a wider range than is generally accepted today, and found that the device maintained pressure in the range for 98% of the time versus only 65% with the manual technique. The same device performed similarly in 9 mechanically ventilated patients.[15] Farré et al[13] and Valencia et al[16] tested a simple cuff pressure regulator and found that it significantly reduced the incidence of low cuff pressure (below 20 cm H_2O), although no difference was observed in the development of ventilator-associated pneumonia.

Like these previously studied devices, the IntelliCuff was able to maintain cuff pressure effectively by keeping it within the acceptable range for ~95% of the time with movement and 99% of the time without movement. Closer examination revealed that the IntelliCuff completely eliminated issues of low cuff pressure, but only partially eliminated high average cuff pressures. The fact that the high pressures occurred more frequently with the manual technique demonstrates that the IntelliCuff is able to moderately, although not completely, control for this phenomenon. This partial adjustment for high cuff pressures is illustrated by the arrows in Figure 6. As shown, the IntelliCuff tends to adjust the baseline cuff pressure, rather than the average cuff pressure, back toward the set pressure. This explains why the average cuff pressure with the IntelliCuff tends to be above the set pressure, although less severely than with the manual technique. Whether this phenomenon also occurs in pneumatic devices and whether it has clinical effects require further investigation.

Unlike other ETT cuff pressure controllers, the IntelliCuff is incorporated into a ventilator and requires no additional equipment. Ferrer and Torres[23] suggested that complexities and cost may be responsible for the lack of clinical use of automatic cuff controllers, and the IntelliCuff may solve the former issue.

Our study adds to a growing body of literature suggesting that cuff pressure management devices are a very promising solution to cuff pressure issues. Sole et al[12] evaluated manual adjustment of cuff pressure in response to an alarm and found that frequent adjustment significantly improved the maintenance of cuff pressure but was labor-intensive. During 12-h shifts, they found that a mean of 8 cuff pressure adjustments were needed to keep cuff pressure within the desirable range, and nonetheless, the proportion of time within 20–30 cm H_2O was 88.9%, noticeably lower than the results obtained with many automatic devices.

Similarly, Jain and Tripathi[17] found that even hourly manual adjustment of cuff pressure was significantly outperformed by an automatic cuff pressure device.

There are certain limitations with each part of this study. First, although the simulated movement was designed to represent possible movement of an intubated patient, the movement itself is distinct from movement realistically seen clinically. Our model made relatively constant and consistent movements for 2 h, which is unlikely in clinical practice. Additionally, due to structural limitations, the movements we were able to generate kept the neck in the same position relative to the head, rather than bending or rotating at the neck, which might have a larger effect on cuff pressure.[24] However, a recent study found that even simple movements similar to those performed in our study can cause significant changes in cuff pressure.[18] The movement allowed us to consider position changes that a patient might experience, creating a more complicated system than the stationary trachea model alone. Second, the silicon tubing trachea model used in the stationary model is consistent with trachea models from previous studies,[19] but it is not a perfect representation of a real trachea in shape or material.[25] Since we were only evaluating the pressure inside the cuff and not the displacement of the tracheal wall or the effectiveness of the seal, our simple model provided a reasonable representation. Third, this study did not test for sudden changes in airway pressure, as might be seen with coughing or gagging, which is an important consideration for automatic cuff pressure controllers. According to Hamilton Medical's Manager of Research and New Technology, Dominik Novotni MD, the IntelliCuff immediately compensates for sudden decreases in cuff pressure but does not respond to increases up to 90 mbar (91.8 cm H_2O) until the pressure has been elevated (defined as set pressure + 4.5 mbar) for longer than 30 s (personal communication, 2014). If the pressure does exceed 90 mbar for > 2 s, it is immediately lowered to 90 mbar, and then the 30-s delay rule is activated. Future studies should be done to evaluate this function. Fourth, as shown in Tables 1 and 2, several of the differences observed in this study were not statistically significant, particularly when the data were broken down to individual PIP settings. We suspect that these differences would become significant if additional runs were performed or the run durations were increased, but further analysis is needed. Finally, all parts of this study were performed on a bench with simulated situations, which is an inherent limitation. Clinical evaluations of the IntelliCuff are needed to verify its effectiveness in patients.

Conclusions

The IntelliCuff significantly reduces the drop in cuff pressure observed when cuff pressure is set manually. In addition, the IntelliCuff is able to completely prevent low average cuff pressures and partially prevent high average pressures. Finally, regardless of technique used to set cuff pressure, cuff pressures change directly with changes in inspiratory airway pressure, although the IntelliCuff is able to partially limit this phenomenon. A follow-up prospective study of the IntelliCuff in mechanically ventilated patients is required. Whether this or other similar devices have the potential to improve patient outcome has not been determined and presents exciting opportunities for future research and development.

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