Is Less More or Is It a Call for Evidence-Based Guidance?

Experienced intensive care clinicians who reminiscence with rosy nostalgia about the care provided to patients who were critically ill and mechanically ventilated decades ago often highlight the frequent monitoring and handling of almost any airway device for respiratory care. In those years, ventilator circuits, in-line suction catheters, heat and moisture exchangers, and even endotracheal tubes were routinely manipulated and exchanged, based on the flawed perception that changing to a new device was safer, irrespective of the effects of these manipulations. Since then, clinical practice in ICUs worldwide has been greatly transformed,[1] driven by robust evidence in favor of the logic that less may be more.[2] Indeed, today we allow patients who receive critical care to heal themselves with the lowest level of supportive care to reduce risks of iatrogenic harm and/or unnecessary costs.

We learned that risk of ventilator-associated pneumonia (VAP), a serious complication of patients who are ventilated,[3,4] was unaffected by routine changes of respiratory care devices. In the latest meta-analysis by Han and Liu[5] of more than 19,000 subjects, a reduced risk of VAP was found as ventilator circuit-change intervals were extended. Likewise, in a study by Thomachot et al,[6] in which daily change of heat and moisture exchangers was compared with a weekly change, VAP did not differ between the groups. As for the in-line closed suction catheters, soon after introduction of these devices in clinical practice, it was common to frequently change them because of the risks of rapid colonization. These assumptions were challenged by Stoller et al,[7] who compared, in 2 subsequent periods, daily or weekly changes of in-line catheters. No differences in VAP cases were found between the 2 periods. A 4.5-fold decrease in catheter costs was achieved in the period of prolonged catheter use. In another randomized clinical trial, Kollef et al[8] evaluated the cost-effectiveness of not routinely changing in-line suction catheters in >500 subjects who required mechanical ventilation. VAP was similar between the groups. Moreover, no differences in other major secondary outcomes were evident, which clearly corroborated the cost-effectiveness of the conservative strategy.

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How does the concept of less is more apply to the management of the endotracheal tube, when taking into account the latest technological advancements in this field? In recent years, improvements have been achieved in the design of the tube, primarily aimed at reducing the risk of VAP.[9] Given the primary role of bacteria-laden subglottic secretions in the pathogenesis of VAP, endotracheal tubes that allow aspiration of subglottic secretions have been developed, with a 50% decrease in VAP incidence in some studies[10] but without consequential improvements in survival. Endotracheal tubes coated with silver[11] and cuffs made of innovative materials and/or shapes were reported to have merit[12] but failed to provide conclusive benefits in clinical trials,[13] which ultimately limits widespread clinical applicability of these innovations.

Another factor in the pathogenesis of VAP is aspiration past the endotracheal tube cuff. Several studies in highly controlled in vitro settings confirmed the role of cuff pressure in preventing aspiration of subglottic secretions.[12,14] Thus, efforts have been made to develop strategies and devices to maintain pressure within the recommended range, specifically 20–30 cm H_2O. As reported by Rello et al,[15] cuff pressure < 20 cm H_2O was a risk factor for the development of VAP. Cuff pressure > 30 cm H_2O may cause tracheal injury by impeding blood flow and causing tissue ischemia.[16] Despite those risks, the appropriate frequency of cuff monitoring is unknown, and health-care providers rely on local hospital policies rather than evidence-based recommendations for routine cuff management. In an Australian survey, significant heterogeneity was reported in the frequency of cuff pressure assessments, which ranged from checks every 4 h to every 24 h.[17] In addition, the providers who were surveyed were also uncertain regarding the most appropriate target cuff pressure.[17]

In this issue of RESPIRATORY CARE, Letvin et al[18] shed some light on the frequency of cuff pressure monitoring. The study focused on the impact of cuff pressure monitoring frequency on pulmonary complications and found

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no difference in major outcomes, which suggests the futility of frequent cuff pressure monitoring. Based on this evidence, would it be reasonable to shift to sporadic cuff pressure monitoring, or should we be cautious about interpreting these new findings? Letvin et al[18] used the algorithm for surveillance of ventilator-associated events[19-21] as the primary outcome by using electronic data from the Barnes-Jewish Hospital, where the study was conducted. A ventilator-associated event is defined by a sudden worsening in oxygenation after a period of stability that requires ventilator adjustments. Ventilator-associated events are commonly associated with conditions other than VAP (eg, atelectasis, acute pulmonary edema, ARDS).[21]

It could be argued that the primary outcome chosen by Letvin et al[18] was limited in detecting effectiveness of frequent cuff pressure control. Maintaining the cuff pressure within the appropriate range reduces micro-aspiration of colonized subglottic secretions and the incidence of VAP, which was only included as a secondary outcome by the researchers. The concept of ventilator-associated events was never intended as a surrogate of VAP, as clearly described by Klompas and collaborators[19,21] in pivotal studies. As expected, Canadian[22] and European[23] studies confirmed inconsistencies between ventilator-associated events and VAP because clinical VAP might occur in only 30% of the ventilator-associated event cases.[23] This raises concerns regarding the methods of the study by Letvin et al[18] because it is possible that many VAP events were overlooked, which reduces the reliability of the chosen measure of effect. Finally, in line with the very low incidence of VAP reported in the latest preventive studies,[11,24] the researchers encountered a lower-than-expected incidence of ventilator-associated events and comparable low numbers of VAP. These low ventilator-associated event/VAP rates raise a question about the overall power of the study in detecting potential differences between groups.

Another point that merits attention concerns the dynamics of endotracheal tube cuff deflation. Little is currently known about how cuffs deflate and the key factors associated with the gradual reduction in internal cuff pressure. These considerations are pertinent to the study by Letvin et al,[18] in which only one endotracheal tube type, the Shiley Hi-Lo (Covidien, Dublin, Ireland), was used for the study. Theoretically, cuff materials and manufacturing features of the cuff pilot balloon may play essential roles in the cuff leakage rate. Thus, the findings by Letvin et al[18] might only pertain to this endotracheal tube, and inferences related to other endotracheal tubes commercially available may not be valid. Along this line of thinking, 2 possibilities might explain the negative findings of this trial. One possibility is that the studied endotracheal tube had exceptional characteristics and was able to maintain the internal cuff pressure within the recommended range, even during infrequent monitoring, which ultimately avoided aspiration. However, previous studies[25] that evaluated standard cuff management versus continuous monitoring do not support this argument because recurrent episodes of hypoinflation of the cuff were encountered. The other option is that, irrespective of the significant deflation of the cuff, the resulting deleterious effects on the studied population were negligible due to the implementation of other VAP prevention strategies that could have offset risks associated with pulmonary aspiration.

It is worth noting that comparative studies of standard versus continuous monitoring[25] also reported frequent cuff hyperinflations. Unfortunately, the study by Letvin and colleagues[18] does not allow us to extrapolate the risks of hyperinflation associated with sporadic checks of the cuff, but it is important to note that tracheal lesions associated with invasive mechanical ventilation are more common than previously thought and are challenging to diagnose due to subtle clinical signs. A study that evaluated postextubation tracheal lesion through bronchoscopic assessments confirmed that overinflation of a tracheal cuff (>30 cm H_2O) was the main determinant of tracheal lesions.[26]

In summary, although respiratory care practice has attempted to reduce unnecessary costs while preserving benefits for patients who are mechanically ventilated, it is prudent to not favor sporadic cuff monitoring based on recent findings by Letvin et al[18] but rather to extend the researchers' study rationale and suggest promising areas for further laboratory and clinical investigations. In particular, although the most recent meta-analysis,[25] including 543 subjects on the effects of continuous cuff monitoring, reported noteworthy reduction of VAP (hazard ratio 0.47, 95% CI 0.31–0.71) and fewer episodes of cuff underinflation, the reasons for limited implementation of this technology are still elusive, and, in the future, applicability will be further challenged by the continuous decrease in VAP incidence worldwide. Investigators should therefore explore potential hurdles in implementing continuous cuff monitoring and further explore possible benefits to promote pervasive acceptance. Moreover, little is known about the main manufacturing features associated with cuff deflation. Thus, we call attention to this seldom-considered issue and emphasize the importance of comprehensive preclinical and clinical studies to appraise cuff deflation mechanisms. This could ultimately encourage engineering advancements to develop next-generation cuffs less prone to variations in internal pressure. Finally, rather than substantiating the merits of less is more in cuff management, the study by Letvin et al[18] raises awareness about the necessity of developing reliable data in this field, which could be applied by medical organizations to provide guidance on the most proficient cuff management to ensure benefits, while reducing complications and health care costs.

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REFERENCES

1. Hess DR, Kallstrom TJ, Mottram CD, Myers TR, Sorenson HM, Vines DL, et al. Care of the ventilator circuit and its relation to ventilator-associated pneumonia. Respir Care 2003;48(9):869-879.
2. Marik PE. "Less is more": the new paradigm in critical care. In: Evidence-based critical care. Cham, Switzerland: Springer International Publishing;2015:7-11.
3. Torres A, Niederman MS, Chastre J, Ewig S, Fernandez-Vandellos P, Hanberger H, et al. International ERS/ESICM/ESCMID/ALAT guidelines for the management of hospital-acquired pneumonia and ventilator-associated pneumonia: Guidelines for the management of hospital-acquired pneumonia (HAP)/ventilator-associated pneumonia (VAP) of the European Respiratory Society (ERS), European Society of Intensive Care Medicine (ESICM), European Society of Clinical Microbiology and Infectious Diseases (ESCMID) and Asociación Latinoamericana del Tórax (ALAT). Eur Respir J 2017;50(3):1700582.
4. Kalil AC, Metersky ML, Klompas M, Muscedere J, Sweeney DA, Palmer LB, et al. Management of adults with hospital-acquired and ventilator-associated pneumonia: 2016 clinical practice guidelines by the Infectious Diseases Society of America and the American Thoracic Society. Clin Infect Dis Off Publ Infect Dis Soc Am 2016;63(5):e61-e111.
5. Han J, Liu Y. Effect of ventilator circuit changes on ventilator-associated pneumonia: a systematic review and meta-analysis. Respir Care 2010;55(4):467-474.
6. Thomachot L, Leone M, Razzouk K, Antonini F, Vialet R, Martin C. Randomized clinical trial of extended use of a hydrophobic condenser humidifier: 1 vs. 7 days. Crit Care Med 2002;30(1):232-237.
7. Stoller JK, Orens DK, Fatica C, Elliott M, Kester L, Woods J, et al. Weekly versus daily changes of in-line suction catheters: impact on rates of ventilator-associated pneumonia and associated costs. Respir Care 2003;48(5):494-499.
8. Kollef MH, Prentice D, Shapiro SD, Fraser VJ, Silver P, Trovillion E, et al. Mechanical ventilation with or without daily changes of in-line suction catheters. Am J Respir Crit Care Med 1997;156(2 Pt 1):466-472.
9. Klompas M. Potential strategies to prevent ventilator-associated events. Am J Respir Crit Care Med 2015;192(12):1420-1430.
10. Caroff DA, Li L, Muscedere J, Klompas M. Subglottic secretion drainage and objective outcomes: a systematic review and meta-analysis. Crit Care Med 2016;44(4):830-840.
11. Kollef MH, Afessa B, Anzueto A, Veremakis C, Kerr KM, Margolis BD, et al. Silver-coated endotracheal tubes and incidence of ventilator-associated pneumonia: the NASCENT randomized trial. JAMA 2008;300(7):805-813.
12. Li Bassi G, Ranzani OT, Marti JD, Giunta V, Luque N, Isetta V, et al. An in vitro study to assess determinant features associated with fluid sealing in the design of endotracheal tube cuffs and exerted tracheal pressures. Crit Care Med 2013;41(2):518-526.
13. Philippart F, Gaudry S, Quinquis L, Lau N, Ouanes I, Touati S, et al. Randomized intubation with polyurethane or conical cuffs to prevent pneumonia in ventilated patients. Am J Respir Crit Care Med 2015;191(6):637-645.
14. Zanella A, Scaravilli V, Isgrò S, Milan M, Cressoni M, Patroniti N, et al. Fluid leakage across tracheal tube cuff, effect of different cuff material, shape, and positive expiratory pressure: a bench-top study. Intensive Care Med 2011;37(2):343-347.
15. Rello J, Soñora R, Jubert P, Artigas A, Rué M, Vallés J. Pneumonia in intubated patients: role of respiratory airway care. Am J Respir Crit Care Med 1996;154(1):111-115.
16. Nordin U. The trachea and cuff-induced tracheal injury. An experimental study on causative factors and prevention. Acta Otolaryngol Suppl 1977;3451-3471.
17. Talekar CR, Udy AA, Boots RJ, Lipman J, Cook D. Tracheal cuff pressure monitoring in the ICU: a literature review and survey of current practice in Queensland. Anaesth Intensive Care 2014;42(6):761-770.
18. Letvin A, Kremer P, Silver PC, Samih N, Reed-Watts P, Kollef MH. A prospective trial of frequent versus infrequent monitoring of endotracheal tube cuff pressures. Respir Care 2018;63(5):495-501.
19. Magill SS, Klompas M, Balk R, Burns SM, Deutschman CS, Diekema D, et al. Developing a new, national approach to surveillance for ventilator-associated events. Crit Care Med 2013;41(11):2467-2475.
20. Klompas M, Kleinman K, Platt R. Development of an algorithm for surveillance of ventilator-associated pneumonia with electronic data and comparison of algorithm results with clinician diagnoses. Infect Control Hosp Epidemiol 2008;29(1):31-37.
21. Klompas M, Khan Y, Kleinman K, Evans RS, Lloyd JF, Stevenson K, et al. Multicenter evaluation of a novel surveillance paradigm for complications of mechanical ventilation. PLoS One 2011;6(3):e18062.
22. Muscedere J, Sinuff T, Heyland DK, Dodek PM, Keenan SP, Wood G, et al. The clinical impact and preventability of ventilator-associated conditions in critically ill patients who are mechanically ventilated. Chest 2013;144(5):1453-1460.
23. Klein Klouwenberg PM, van Mourik MS, Ong DS, Horn J, Schultz MJ, Cremer OL, et al. Electronic implementation of a novel surveillance paradigm for ventilator-associated events: Feasibility and validation. Am J Respir Crit Care Med 2014;189(8):947-955.
24. Li Bassi G, Panigada M, Ranzani OT, Zanella A, Berra L, Cressoni M, et al. Randomized, multicenter trial of lateral Trendelenburg versus semirecumbent body position for the prevention of ventilator-associated pneumonia. Intensive Care Med 2017;43(11):1572-1584.
25. Nseir S, Lorente L, Ferrer M, Rouzé A, Gonzalez O, Bassi GL, et al. Continuous control of tracheal cuff pressure for VAP prevention: a collaborative meta-analysis of individual participant data. Ann Intensive Care 2015;5(1):43.
26. Touat L, Fournier C, Ramon P, Salleron J, Durocher A, Nseir S. Intubation-related tracheal ischemic lesions: incidence, risk factors, and outcome. Intensive Care Med 2013;39(4):575-582.