Sherpa Suction™ Guide and Sherpa Suction System Abstract Booklet

Ciel Medical

Current scientific evidence supports the use of above the cuff suctioning as a basic standard of practice to minimize pooling of secretions above the ETT cuff to prevent ventilator-associated pneumonia (VAP) and ventilator-associated events (VAEs) in adult patients.

The following abstracts have been extracted from various journals and resources to provide scientific evidence supporting suctioning above the endotracheal tube (ETT) cuff for removal of secretions in orally intubated patients.

LITERATURE REVIEW SUMMARY

Ventilator-associated pneumonia is a clinical entity leading to significant increased morbidity and mortality in mechanically ventilated patients. VAP can occur when bacterial colonized secretions from the oropharynx or stomach are aspirated into the lower respiratory track. These bacteria-rich secretions can pool in the oropharynx or subglottic space above the endotracheal tube cuff. Removal of these secretions is one strategy for reducing VAP. Multiple randomized control trials including over 3,100 patients and subsequent meta-analyses have examined subglottic suctioning as an intervention to reduce VAP incidence. These trials have demonstrated a significant reduction in VAP, with studies ranging from 40-67% VAP reduction, with some studies reporting secondary outcomes in reduced antibiotic exposure, delayed onset of VAP, decreased length of mechanical ventilation, and decreased length of ICU stay. A small number of case reports have shown complications due to damage of the tracheal mucosa with high frequency or continuous subglottic suction, but no increase in mortality has been seen with subglottic suctioning.

ABSTRACTS

Subglottic Suctioning

a) Meta-Analyses

Roquilly 2015: This publication is a meta-analysis of strategies to prevent hospital acquired pneumonia and the effect on ICU mortality. This study included 157 studies totaling 37,156 patients with 21 different interventions. Subglottic suctioning had no change in the primary outcome, ICU mortality (RR 0.98, 95% CI 0.84-1.15). In secondary outcomes, subglottic secretions reduced hospital acquired pneumonia (RR 0.56 95% CI 0.46-0.67).

Wang 2012: This meta-analysis identified 10 randomized controlled trials with 2213 patients comparing subglottic suctioning to standard care. Subglottic suctioning decreased VAP incidence (RR 0.56, 95% CI 0.45-0.59), average number of ventilated days (-1.55 days, 95% CI -2.4 to -0.71) and increased time to VAP (3.9 days, 95% CI 2.36-5.24). The authors did further subgroup analysis, demonstrating that with intermittent subglottic suctioning the relative risk of VAP was 0.49 (95% CI 0.34-0.71) whereas the relative risk of VAP with continuous subglottic suctioning was 0.61 (95% CI 0.46-0.79).

Frost 2011: This meta-analysis combined nine randomized control trials of intermittent subglottic suctioning which included 2280 patients. Intermittent subglottic suctioning reduced VAP incidence (RR 0.52, 95% CI 0.42-0.65). When analysis was limited to studies of patients who were anticipated to require >48 hours of mechanical ventilation, subglottic suctioning significantly reduced average number of mechanical ventilation days by two days (95% CI 1.6-2.3).

Muscedere 2011: Thirteen randomized control trials of subglottic suctioning versus standard care were included in this meta-analysis, covering 2442 patients. Subglottic suctioning reduced the incidence of VAP (RR 0.55, 95% CI 0.46-0.66), ICU length of stay (-1.52 days, 95% CI -2.94 to -0.11), and mechanical ventilation days (-1.08 days, 95% CI -2.04 to -0.12) and increased time to initial VAP (2.66 days, 95% CI 1.06-4.26). There were no adverse events and no change in mortality.

Dezfulian 2005: In this publication, five randomized control studies met inclusion criteria for meta-analysis, covering 896 patients. Subglottic suctioning (either continuous or intermittent) reduced VAP with a relative risk of 0.51 (95% CI 0.37-0.71). The authors also concluded subglottic suctioning reduced length of mechanical ventilation and hospital stay and delayed onset of VAP, however the later results were only significant after excluding one outlier trial.

Conclusions from meta-analyses:

Five meta-analyses were reviewed which examined the effect of subglottic suctioning on pneumonia (hospital-acquired or ventilator-associated) incidence. All five studies concluded that subglottic suctioning significantly reduced pneumonia incidence by 44-49%. No major adverse events were reported and subglottic suctioning had no effect on mortality. Subglottic suctioning also improved secondary clinically relevant outcomes of reduced duration of mechanical ventilation and delayed onset of VAP.

b) Randomized, Controlled Clinical Trials

Damas 2015: In this prospective, randomized control trial in 5 ICUs in the same large European hospital, 352 patients who were ventilated with the Teleflex Isis Endotracheal Tube for >48 hours were randomized to receive standard care (182 patients) or subglottic suctioning at an undefined frequency (170 patients). VAP incidence (as defined by a cultured pathogen and clinical evidence of pneumonia) was significantly reduced in patients who received subglottic suctioning (8.8% versus 17.6%, p=0.018). Additionally, antibiotic consumption was reduced in the subglottic suctioning cohort with significantly fewer antibiotics days (61.6% vs 68.5% of ICU days, p<0.0001). No significant differences were observed in hospital mortality.

Lorente 2014: In this single center study, 656 ICU patients were intubated with a Mallinckrodt HiLo Evac ETT or standard ETT (methodology for ETT assignment not given) and randomized based on room number to receive continuous control of ETT cuff pressure or standard care. The authors founds that the combination of subglottic suctioning and continuous control of ETT cuff pressure (71 patients) significantly reduced ventilator associated respiratory infections and daily health care costs as compared to standard care (241 patients), continuous control of cuff pressure alone (260 patients), and subglottic suctioning alone (84 patients). Unfortunately, randomization in this study was limited and significant variability in medical acuity and type of admission existed between cohorts, likely causing significant confounding and making the independent effect of subglottic suctioning and cuff pressure control challenging to interpret.

Lacherade 2010: This is a multicenter, prospective randomized control trial of 333 patients admitted to four different medical or surgical ICUs who were anticipated to require >48 hours intubation. All patients were intubated with a Mallinckrodt HiLo Evac ETT and randomly assigned to hourly subglottic suctioning versus usual care. VAP incidence was significantly reduced in patients receiving intermittent subglottic suctioning (14.8% versus 25.6% p=0.02). There was no difference in duration of mechanical ventilation and in-hospital mortality.

Bouza 2008: This is a prospective, randomized control trial of 690 patients who underwent major heart surgery who were randomized to continuous aspiration of subglottic suctioning (CASS) using a Mallincrodt HiLo Evac ETT (359 patients) compared to patients who were intubated with standard endotracheal tubes without subglottic suctioning (331 patients). VAP incidence was non-statistically (p=0.2) reduced in the CASS population (3.6% vs 5.3%) and antibiotic use as measured by daily defined doses was significantly reduced (p<0.001) in CASS population (1213 vs 1932). In a subgroup analysis of patients ventilated for >48 h, there was a statistically significant reduction of VAP incidence in the CASS cohort (26.7% vs 47.5%), decreased ICU length of stay (7 days vs 16.5 days), and decreased daily defined doses of antibiotics (1206 vs 1877). No adverse events (including obstruction of the aspiration tube lumen) were observed.

Lorente 2007: This is a prospective, single center randomized control trial of 280 patients in a medical-surgical ICU expected to require mechanical ventilation for >24 hours. Patients were randomized to a conventional ETT versus SealGuard Evac ETT (ultrathin polyurethane cuff with subglottic suction lumen) with subglottic suctioning every hour. VAP incidence was statistically reduced in the subglottic suctioning/polyurethane cuff cohort (7.9% versus 22.1%, p=0.001).

Smulders 2002: This is a prospective, single center randomized control trial. One hundred and fifty (150) patients admitted to the ICU and expected to require >72 hours mechanical ventilation were intubated with a standard endotracheal tube (75 patients) or a ETT with subglottic suction lumen (75 patients, ETT brand not specified). Subglottic suctioning was performed intermittently by automated vacuum system at 20 second intervals. In the study population, VAP incidence was significantly reduced in the subglottic suctioning group (4% versus 12%, p=0.014). No effect was seen on mortality, length of ICU stay, or length of hospital stay.

Kollef 1999: This is a prospective, single center, randomized control trial of 343 patients in the cardiothoracic ICU who underwent cardiac surgery and required mechanical ventilation. All patients were intubated with Mallincrodt HiLo Evac ETT and then randomized to receive CASS (160 patients) versus standard care with no subglottic suctioning (183 patients). VAP incidence was non-statistically reduced in the CASS cohort (5% vs 8.2%, p=0.238). Onset of VAP was significantly delayed 5.6 ± 2.3 days (mean ± SD) versus 2.9 ± 1.2 days though this had no effect on secondary outcomes of lobar atelectasis, duration of mechanical ventilation, length of ICU or hospital stay, hospital mortality, or acquired organ system derangement. However, the study was a single center trial and underpowered for the observed VAP difference. No adverse events were associated with CASS however a patient

did undergo an unnecessary bronchoscopy after the radiopaque marker on the ETT was misinterpreted as an aspirated tooth on routine imaging.

Valles 1995: In this single center, prospective randomized control trial, 190 patients admitted to an ICU who were anticipated to require >72 hours mechanical were intubated with a Mallinckrodt HiLo Evac ETT and randomized to receive CASS (76 patients) versus standard care (77 patients). VAP incidence was reduced in the CASS cohort (19.9 episodes/1000 ventilator days versus 39.6 episodes/1000 ventilator days) and a significantly later onset of VAP incidence was also observed, with CASS patients having onset of VAP at 12 ± 7.1 days (mean ± SD) versus 5.9 ± 2.1 for standard care.

Mahul 1992: In this study, 145 mechanically ventilated patients in a single ICU were all intubated with a Mallinckrodt Hi-Lo Evac ETT and randomized to standard care (75 patients) or hourly subglottic suctioning (70 patients). Patients were then randomized a second time to stress ulcer prophylaxis with sucralfate or aluminum hydroxide. The subglottic suctioning cohort had a lower incidence of pneumonia (13% versus 29.1%, $p<0.05$) with delayed onset of pneumonia (8.3±5 days versus 16.2±11 days, mean ± SD).

Conclusions from randomized studies: Nine randomized control trials spanning various clinical populations (medical, surgical, cardiac) and over 3,100 patients were examined. Five trials demonstrated significant reduction in VAP incidence with subglottic suctioning alone. Two additional trials had significant reduction in VAP incidence when combined with other VAP-reduction strategies (ultrathin ETT cuffs, continuous cuff pressure monitoring). One trial found significant reduction in VAP incidence with subglottic suctioning when subgroup analysis was limited to patients who were mechanically ventilated for >48 hours. Reduction in VAP incidence ranged from 40-67% in these trials. Two trials also found reduced antibiotic requirements in patients receiving subglottic suctioning, leading to lower antibiotics costs and improving antibiotic stewardship. Subglottic suctioning had no effect on mortality and no major adverse events were reported in these studies.

c) Retrospective Studies

Hudson 2015: This is a retrospective study of 4880 patients undergoing cardiac surgery and admitted to the ICU at the University of Ottawa Heart Institute where CASS was initiated for all intubated cardiac surgery patients. There were 2430 patients in the pre-CASS cohort and 2450 patients who received CASS. Pneumonia incidence was reduced in the CASS cohort (1.9% vs 5.6%, $p<0.0001$). Secondary outcomes were also improved with CASS, with decreased 30 day in hospital mortality (2.1% vs 3.3% $p=0.007$), decreased median ventilator time (8.42 hours versus 7.3 hours $p<0.0001$), and ICU length of stay (1.77 days versus 1.17 days $p<0.0004$). In multivariate analysis, CASS was an independent protective predictor for pneumonia with a relative risk of 0.342 (95% confidence interval 0.239-0.490).

d) Observational studies

Rello 1996: In this prospective single center study of 83 patients, all patients were intubated with a Mallinckrodt Hi-Lo ETT and treated with continuous subglottic suctioning. Cases were patients who developed VAP in the first eight days of mechanical ventilation and controls were those who were not diagnosed with VAP. Subglottic suctioning failure was present in 42.9% of cases and 30.6% of controls. In multivariate analysis, failure of subglottic suctioning was significantly associated with development of VAP (RR 5.2, 95% CI 1.24-22.64). The mechanism through which subglottic suctioning failed was not reported.

<u>Oropharyngeal Suctioning</u>

a) Observational Studies

Chao 2009: This is a single center observational study. For patients admitted to the general ICU, 159 consecutive patients were enrolled to receive standard care. Several months later, 102 consecutive patients were enrolled after nursed were educated about performing oral suctioning for 10 seconds prior to every position change. VAP incidence was significantly reduced with introduction of oral suctioning (4.9% with suctioning versus 15.1%, $p<0.001$).

Tsai 2008: In this prospective study, 237 patients were observed in the control phase and 227 patients were enrolled following nursing education to perform oral suctioning prior to every position change. VAP incidence was significantly reduced after introducing routine oral suctioning (2.6% vs 11% $p<0.001$). Oral suctioning also

reduced number of mechanical ventilation days (20.2 ± 4.0 days versus 28.8 ±17.2, p=0.009) and length of ICU stay (20.3 ± 4.0 vs 27.6 ± 17.0, p=0.012).

Conclusions for oropharyngeal suctioning: Two observation studies have demonstrated reduced VAP incidence after implementation of routine oral suctioning in intubated ICU patients prior to every position change. No adverse events were reported. No randomized clinical trials or comparisons to other VAP reducing strategies were identified.

Case reports of Subglottic Suctioning Complications

Over more than 25 years of clinical use, some complications have been reported in the literature for subglottic suctioning. Relevant case reports and small case series are reviewed here.

Failure of Subglottic Suction Lumen

Dragoumanis 2007: This is a case series of 40 patients intubated with a Mallinckrodt HiLo Evac ETT with continuous subglottic suctioning. Nineteen of the 40 patients (48%) had failure of the subglottic suction port. Endoscopic evaluation of the dysfunctional suction port was performed and identified aspiration of adjacent tracheal mucosa in 17 patients, occlusion by thick secretions in 1 patient, and no identifiable cause in 1 patient due to poor endoscopic visualization.

Laryngeal Edema

Girou 2004: This is a small randomized control trial of 18 patients who required mechanical ventilation for more than 5 days. Patients were intubated with a Mallinckrodt HiLo Evac ETT and randomized to receive continuous subglottic suctioning and semi-recumbent positioning (8 subjects) versus standard care (10 subjects). There was no significant difference in bacterial airway colonization and the study was not powered to detect differences in VAP incidence. Five of the 10 subjects in the continuous subglottic suctioning/semi-recumbent positioning cohort were extubated during the study period, with two of those five developing laryngeal edema and requiring re-intubation. This was a higher percentage than the 2-7% commonly reported. This was hypothesized to be the result of injury of the tracheal mucosa due to continuous suctioning but the study was not powered to measure this outcome.

Tracheal Injury

Suys 2013: This is a case series of six consecutive ICU patients intubated with a Mallinckrodt TaperGuard Evac ETT. Subglottic suctioning was performed every 15 seconds via an automated vacuum suction device. After 24 hours, high resolution CT imaging was performed, demonstrating entrapment of the tracheal mucosa in the subglottic suction orifice.

Harvey 2007: This case report describes two patients who were intubated with Mallinckrodt HiLo Evac ETT and treated with continuous subglottic suctioning. One patient was found to have a tracheoesophageal fistula while undergoing tracheostomy after 35 days of orotracheal intubation. A second patient developed a tracheoesphageal fistula after 22 days of orotracheal intubation. In both instances, the location of the tracheal fistula was felt to correspond to the dorsal subglottic suction orifice. A third patient was observed on CT to have invagination of the tracheal mucosa in the suction orifice. However, this patient did not develop any clinical significant tracheal injury.

Conclusions: Several studies have identified damage to tracheal mucosa and failure of suctioning as potential complications of subglottic suctioning. These adverse events are associated with specialized endotracheal tubes with dorsal subglottic suction orifices and continuous or high frequency (every 15 seconds), intermittent suctioning. Less frequent intermittent subglottic suctioning such as every 1 hour which has been employed in several randomized control trials (Lacherade 2010, Lorente 2007, and Mahul 1992) may not have these risks. Additionally, the clinically significant ramifications of tracheal mucosal entrapment, fistula formation and re-intubation, have only been described in case reports of two patients with prolonged orotracheal intubation (Harvey 2007) and two patients in a small randomized trial (Girou 2004). Multiple large randomized control trials and meta-analyses have observed no increased mortality with subglottic suctioning.

BIBLIGRAPHY

Citation	*Authors*	*Title*	*Reference*
AACN 2008	American Association of Critical Care Nurses (AACN)	VAP Practice Alert	Aacn.org, 2008
Bouza 2008	Bouza E, Perez MJ, Munoz P, Rincon C, Barrio JM, Hortal J	Continuous Aspiration of Subglottic Secretions in the Prevention of Ventilator-Associated Pneumonia in the Postoperative Period of Major Heart Surgery	Chest. 2008; 134(5): 938-46. PMID 18641114
Chao 2009	Chao YF, Chen YY, Wang KW, Lee RP, Tsai H	Removal of Oral Secretion Prior to Position Change Can Reduce the Incidence of Ventilator-Associated Pneumonia for Adult ICU Patients: A Clinical Controlled Trial Study	J Clin Nurs. 2009; 18(1): 22-8. PMID 19120729
Chastre 2002	Chastre J and Fagon JY	Ventilator-Associated Pneumonia	Am J Respir Crit Care Med. 2002; 165(7): 867-903. PMID 11934711
Damas 2015	Damas P, Frippiat F, Ancion A, Canivet JL, Lambermont B, Layios N, Massion P, Morimont P, Nys M, Piret S, Lancellotti P, Wiesen P, D'orio V, Samalea N, Ledoux D	Prevention of Ventilator-Associated Pneumonia and Ventilator-Associated Conditions: A Randomized Control Trial with Subglottic Secretion Suctioning	Crit Care Med. 2015; 43(1): 22-30. PMID 25343570
Dezfulian 2005	Dezfulian C, Shojania K, Collard HR, Kim HM, Matthay MA, Saint S	Subglottic Secretion Drainage for Preventing Ventilator-Associated Pneumonia: a Meta-Analysis	Am J Med. 2005; 118(1): 11-8. PMID15639202
Dragoumanis 2007	Dragoumanis CK, Vretzakis GI, Papaioannou VE, Didilis VN, Vogiatzaki TD, Pneumatikos IA	Investigating the Failure to Aspirate Subglottic Secretions with the Evac Endotracheal Tube	Anesth Analg. 2007; 105(4): 1083-5. PMID 17898392
Frost 2013	Frost SA, Azeem A, Alexandrou E, Tam V, Murphy JK, Hunt L, O'Regan W, Hillman KM	Subglottic Secretion Drainage for Preventing Ventilator Associated Pneumonia: A Meta-Analysis	Aust Crit Care. 2013 Nov;26(4):180-8. PMID 23583261
Girou 2004	Girou E, Buu-Hoi A, Stephan F, Novara A, Gutmann L, Safar M, Fagon JY	Airway Colonisation in Long-Term Mechanically Ventilated Pateints: Effect of Semi-Recumbent Position and Continuous Subglottic Suctioning	Intensive Care Med. 2004; 30(2): 225-33. PMID 14647884
Harvey 2007	Harvey RC, Miller P, Bowton DL, MacGregor DA	Potential Mucosal Injury Related to Continuous Aspiration of Subglottic Secretion Device	Anesthesiology. 2007; 107(4); 666-9.
Hudson 2015	Hudson JK, McDonald BJ, MacDonald JC, Ruel MA, Hudson CC	Impact of Subglottic Suctioning on the Incidence of Pneumonia after Cardiac Srugery: A Retrospective Observational Study	J Cardiothorac Vasc Anesth. 2015; 29(1): 59-63. PMID 25169897
ICSI 2011	Institute for Clinical Systems Improvement	Prevention of Ventilator Associated Pneumonia.	Health Care Protocol. Bloominton (MN): Institue for Clinical Systems Improvement (ICSI); 2011.
Klompas 2014	Klompas M, Branson R, Eichenwald E, Greene LR, Howell MD, Lee G, Magill SS, Maragakis LL, Priebe GP, Speck K, Yokoe DS, Berenholtz SM	Strategies to Prevent Ventilator Associated Pneumonia in Acute Care Hospitals: 2014 Update	Infect Control Hosp Epidemiol 2014; 35(8): 915-936. PMID 25026607

Citation	*Authors*	*Title*	*Reference*
Kollef 1999	Kollef MH, Skubas NJ, Sundt TM	A Randomized Clinical Trial of Continuous Aspiration of Subglottic Secretions in Cardiac Surgery Patients	Chest. 1999; 116(5): 1339-46. PMID 10559097
Lacherade 2010	Lacherade JC, De Jonghe B, Guezennec P, Debbat K, Hayon J, Monsel A, Fangio P, Appere de Vecchi C, Ramaut C, Outin H, Bastuji-Garin S	Intermittent Subglottic Secretion Drainage and Ventilator-Associated Pneumonia: a Multicenter Trial	Am J Respir Crit Care Med. 2010; 182(7): 910-7. PMID 20522796
Lorente 2007	Lorente L, Lecuona M, Jimenez A, Mora ML, Sierra A	Influence of an Endotracheal Tube with Polyurethane Cuff and Subglottic Secretion Drainage on Pneumonia	Am J Respir Crit Care Med. 2007; 176(11): 1079-83. PMID 17872488
Lorente 2014a	Lorente L, Lecuona M, Jimenez A, Cabrera J, Mora ML	Subglottic Secretion Drainage and Continuous Control of Cuff Pressure Used Together Save Health Care Costs	Am J Infect Control. 2014; 42(10): 1101-5. PMID 25278402
Mahul 1992	Mahul P, Auboyer C, Jospe R, Ros A, Guerin C, el Khouri Z, Galliez M, Dumont A, Gaudin O	Prevention of Nosocomial Pneumonia in Intubated Patients: Respective Role of Mechanical Subglottic Secretions Drainage and Stress Ulcer Prophylaxis	Intensive Care Med. 1992;18(1):20-5. PMID 1578042
Muscedere 2011	Muscedere J, Rewa O, McKechnie K, Jiang X, Laporta D, Heyland DK	Subglottic Secretion Drainage for the Prevention of Ventilator-Associated Pneumonia: a Systematic Review and Meta-Analysis	Crit Care Med. 2011; 39(8): 1985-91. PMID 21478738
Rello 1996	Rello J, Sonora R, Jubert P, Artigas A, Rue M, Valles J	Pneumonia in Intubated Patients: Role of Respiratory Airway Care	Am J Respir Crit Care Med. 1996;154(1):111-5. PMID 8680665
Roquilly 2015	Roquilly A, Marret E, Abraham E, Asehnoune K	Pneumonia Prevention to Decrease Mortality in Intensive Care Unit: A Systematic Review and Meta-Analysis	Clin Infect Dis. 2015 Jan 1;60(1):64-75. PMID 25252684
Smulders 2002	Smulders K, van der Hoeven H, Weers-Pothoff I, Vandenbroucke-Grauls C	A Randomized Clinical Trial of Intermittent Subglottic Secretion Drainage in Patients Receiving Mechanical Ventilation	Chest. 2002; 121(3): 858-62. PMID 11888973
Suys 2013	Suys E, Nieboer K, Stiers W, De Regt J, Huyghens L, Spapen H	Intermittent Subglottic Secretion Drainage May Cause Tracheal Damage in Patients with Few Oropharyngeal Secretions	Intensive Crit Care Nurs. 2013; 29(6): 317-20. PMID 23727136
Tsai 2008	Tsai HH, Lin FC, Chang SC	Intermittent Suction of Oral Secretions Before Each Positional Change May Reduce Ventilator-Associated Pneumonia: A Pilot Study	Am J Med Sci. 2008; 336(5): 397-401. PMID 19011396
Valles 1995	Valles J, Artigas A, Rello J, Bonsoms N, Fontanals D, Blanch L, Fernandez R, Baigorri F, Mestre J	Continuous Aspiration of Subglottic Secretions in Preventing Ventilator-Associated Pneumonia	Ann Intern Med. 1995; 122(3): 179-86. PMID 7810935
Wang 2012	Wang F, Bo L, Tang L, Lou J, Wu Y, Chen F, Li J, Deng X	Subglottic Secretion Drainage for Preventing Ventilator-Associated Pneumonia: an Updated Meta-Analysis of Randomized Control Trials	J Trauma Acute Care Surg. 2012 May;72(5):1276-85. PMID 22673255
Zolfaghari 2011	Zolfaghari PS, Wyncoll DLA	The Tracheal Tube: Gateway to Ventilator-Associated Pneumonia	Crit Care. 2011; 15(5) 310. PMID 21996487.