



SHOULD MINI-BAL WITH THE COMBICATH BE A PART OF YOUR VAP TREATMENT PLAN?

What is Mini-BAL?

Mini-BAL, such as the Combicath, is a non bronchoscopic bedside method of performing a small volume (“Mini”) broncho-alveolar lavage (BAL) for gram stain and/or quantitative culture.

What role would Combicath play in your treatment strategy?

While Combicath has been shown to yield culture results comparable to those derived from directed bronchoscopic BAL, Combicath is not intended to replace the “gold standard” bronchoscopy. Mini-BAL’s intended role in an effective microbiologic evidence based VAP treatment strategy is to provide the health care team with an alternative non-bronchoscopic method of acquiring diagnostic quality lower airway specimens when bronchoscopy is not warranted or readily available.

Why should you consider a more invasive microbiology based approach?

The primary reason is to provide reliable quantitative culture evidence to guide the specific antibiotic therapy prescribed for every patient suspect of VAP. In actual practice, today’s thoughtful empiric antibiotic choices and pharmacy protocols are often providing appropriate coverage for symptomatic patients. But, increasingly, the goal of monotherapy by day 3 is harder to accomplish without microbiologic culture evidence.

Additionally, gram stains from tracheal aspirates often yield false positives due to a high number of organisms grown from the ET tube that has been colonized. Today many hospitals are utilizing the gram stain of the Combicath to direct initial antibiotic because it provides a high quality sample that is rarely contaminated with squamous epithelial cells or colonizers.

In fact, the American Thoracic Society (ATS) and the Infectious Disease Society of America (IDSA) have recently published new recommendations and guidelines which recommend aggressive early empiric antibiotic coverage with immediate acquisition of culture, lower airway samples, and the adjustment of the initial coverage based on the culture results as soon as they are available (~ 48 hours).

“The major goals of this evidence-based guideline for the management of HAP, VAP, and HCAP emphasize early, appropriate antibiotics in adequate doses, while avoiding excessive antibiotics by de-escalation of initial antibiotic therapy, based on microbiologic cultures and the clinical response of the patient, and shortening the duration of therapy to the minimum effective period”, the authors write.

Is there any additional risk to the patient with an invasive sampling program?

The risks associated with bronchoscopy are relatively small, and are well known. Since the blind, bedside mini-BAL is a relatively new procedure to the United States, the available published literature is less than that for bronchoscopy, but the data that are published reflect similar low rates of complications. The blind placement of Combicath catheters at the bedside by respiratory therapists or nurses, as opposed to physicians, suggests the potential for an increased risk to some. These potential risks, however, may be offset by the following differences in Combicath and bronchoscopy:

- The physicians control the ordering of which sampling method will be performed, so they would presumably only order non-bronchoscopic sampling on patients that they are comfortable should tolerate the procedure;
- Combicath catheters are significantly smaller in diameter than bronchoscopes, so the risk of airway restriction and de-saturization is minimized;
- The Combicath procedure typically only requires the sampling catheter to be in the airway for 1 to 2 minutes, so the short procedure time also minimizes airway disruption as well as the patient's tendency to "fight" the catheter;
- Combicath lavage volumes are significantly smaller than those used in bronchoscopy, so there is less residual fluid in the lung, resulting in quick post-procedure patient stabilization and recovery times.

Will blind samplings yield clinically usable results?

A blindly placed Combicath catheter will end up in the right lung in the majority of the procedures. The evidence-based ATS and IDSA guidelines specifically state that "due to the bilateral nature of VAP" lower airway samples can be acquired bronchoscopically or non-bronchoscopically. While this position is understandably drawn from many different literature sources, it may be simplistically summarized by the following statement:

Some Mini-BAL catheters claim to be "directable", but the fact remains that the procedure is blind, so the user has no means of confirming the actual catheter location.

With the more documented diffuse nature of VAP, the actual location of the catheter tip may not be of significance. If the suspect disease is obviously and/or predominantly on the left side, most physicians would opt for bronchoscopy over blind Mini-BAL.

More importantly, a September 2005 study written by Brun-Buisson in CHEST showed that a blind protected catheter yielded the "similar" results as a bronchoscopic directed catheter. **It stated that directionality is not nearly as important as simply getting a quantitative culture.**

On which aspects of the mini-BAL should you focus?

1. ***The Quality of the Sample.*** Since crucial antibiotic decisions are made based on the sample obtained during a mini-BAL procedure, it is important to yield a clean, uncontaminated sample. **Only the Combicath™ has a plugged tip to avoid upper airway contamination.** This polyethylene-glycol tip will not “scoop up” the upper airway contamination like an open catheter and protects the inner sampling catheter from contamination. In an abstract from University of Cincinnati in 2002, the authors documented a 3% contamination rate while using the Combicath.

In fact, the recently updated hospital acquired pneumonia guidelines from the American Thoracic Society (ATS) and Infectious Disease Society of America (IDSA) state “samples contaminated by upper airway secretions as reflected by a high percentage of squamous epithelial cells should be used with caution.” (ATS Guidelines, Feb. 2005, p. 397)

2. ***Patient Safety and Tolerance.*** More importantly, in order to increase patient tolerance of the mini-BAL procedure, the ideal catheter will utilize:

- 1) small lavage volume - 20-40cc's using a single aliquot
- 2) small catheter diameter – (6, 8 or 13 French) for minimal obstruction of airway
- 3) short time spent in the lower lung - 30-90 seconds

3. ***Education.*** Proper education and training for the procedure is necessary for both physicians and respiratory staff:

- 1) The Physician educational process covers the following:
 - The adjunctive role of Combicath to bronchoscopy in meeting new ATS guidelines microbiologic culture based antibiotic use.
 - The importance of early sampling and culture availability.
 - The potential for use of lower airway gram stain for initial empiric guidance.
 - The evolution of effective protocols.
 - The importance of departmental compliance and uniformity in treatment methods.
- 2) The Respiratory Staff should be trained in order to ensure proper technique in order for the procedure to be successful. Please contact your sales representative for training videos, competencies, policies/procedures and inservicing.

American Thoracic Society Updates Guidelines on Hospital-Acquired Pneumonia CME

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[Disclosures](#)

To earn CME credit, read the news brief along with the CME information that follows and answer the post test questions.

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Feb. 16, 2005 — The American Thoracic Society (ATS) has updated their guidelines on hospital-acquired pneumonia (HAP) and also addresses health care-associated pneumonia (HCAP) and ventilator-associated pneumonia (VAP). The updated guidelines, which incorporate new information on bacteriology, patient stratification, diagnostic evaluation, antibiotic therapy, and prevention, are published in the Feb. 15 issue of the *American Journal of Respiratory & Critical Care Medicine*.

"Since the initial 1996 ATS guideline on nosocomial pneumonia, a number of new developments have appeared, mandating a new evidence-based guideline for hospital-acquired pneumonia (HAP), including healthcare-associated pneumonia (HCAP) and ventilator-associated pneumonia (VAP)," write Michael S. Niederman, MD, from the ATS, and colleagues. "This document, prepared by a joint committee of the ATS and Infectious Diseases Society of America (IDSA), focuses on the epidemiology and pathogenesis of bacterial pneumonia in adults, and emphasizes modifiable risk factors for infection."

The guidelines review the microbiology of HAP, with an emphasis on multidrug-resistant (MDR) bacterial pathogens, such as *Pseudomonas aeruginosa*, *Acinetobacter* species, and methicillin-resistant *Staphylococcus aureus*. Controversies regarding diagnosis addressed by the guidelines include the importance of initial examination of lower respiratory tract samples for bacteria, and the rationale for both clinical and bacteriologic approaches, using either semiquantitative or quantitative microbiologic methods that help direct selection of appropriate antibiotic therapy. The guidelines also suggest additional diagnostic and therapeutic evaluations for patients with nonresolving pneumonia.

This evidence-based document emphasizes the issues of VAP because there are far fewer available data concerning HAP in nonintubated patients and concerning HCAP. By extrapolation, the guidelines suggest that patients who are not intubated and mechanically ventilated should be treated like patients with VAP, using the same approach to identify risk factors for infection with specific pathogens.

"The major goals of this evidence-based guideline for the management of HAP, VAP, and HCAP emphasize early, appropriate antibiotics in adequate doses, while avoiding excessive antibiotics by de-escalation of initial antibiotic therapy, based on microbiologic cultures and the clinical response of the patient, and shortening the duration of therapy to the minimum effective period," the authors write.

Patients with pneumonia should be treated empirically, targeting the likely pathogens. However, the guideline acknowledges that bacteriology varies from one hospital to another and from one period to another and recommends considering local microbiologic data when adapting treatment recommendations to any specific clinical setting.

The initial empiric antibiotic therapy algorithm includes two groups of patients. Patients with early-onset HAP, VAP, or HCAP and no risk factors for MDR pathogens have no need for broad spectrum therapy. The second group requires broad-spectrum therapy because of late-onset pneumonia or other risk factors for infection with MDR pathogens.

Selected key recommendations from these evidence-based guidelines are as follows:

- HCAP is included in the spectrum of HAP and VAP, and these patients should be treated for MDR pathogens.
- Although a lower respiratory tract culture should be collected from all patients before starting antibiotics, culture collection should not delay the initiation of therapy in critically ill patients.
- Either semiquantitative or quantitative culture data are appropriate for the management of patients with HAP.
- Lower respiratory tract cultures can be obtained by bronchoscopy or by other means and can be cultured quantitatively or semiquantitatively.
- Quantitative cultures increase specificity of the diagnosis of HAP without harmful consequences. Local expertise and experience should influence the choice of specific quantitative technique.
- Negative lower respiratory tract cultures in a patient who has not changed antibiotics in the past 72 hours can be used to stop antibiotic therapy.
- Early, appropriate, broad-spectrum antibiotic therapy should be prescribed in sufficient doses to optimize antimicrobial efficacy.
- Empiric therapy should include agents from a different antibiotic class than the patient has received recently.
- When treating HAP, combination therapy for a specific pathogen should be used judiciously. Consideration should be given to short-duration (five days) aminoglycoside therapy when used in combination with a β -lactam to treat *P. aeruginosa* pneumonia.
- Linezolid is an alternative to vancomycin. Unconfirmed, preliminary data suggest that linezolid may be better than vancomycin for proven VAP caused by methicillin-resistant *S. aureus*.
- Colistin should be considered in patients with VAP caused by a carbapenem-resistant *Acinetobacter* species.
- Aerosolized antibiotics may be helpful as adjunctive therapy in patients with VAP caused by some MDR pathogens.

- Based on the patient's clinical response and the results of lower respiratory tract cultures, deescalation of antibiotics should be considered.
- A shorter duration of antibiotic therapy (seven to eight days) is recommended for patients with uncomplicated HAP, VAP, or HCAP who have received initially appropriate therapy and have had a good clinical response provided they have no evidence of infection with nonfermenting Gram-negative bacilli.

Some of the authors report various financial arrangements with Introbiotics Pharmaceuticals, Inc; Pfizer, maker of ampicillin-sulbactam and linezolid; Wyeth; Brahms; Bristol-Myers Squibb; Cubist Pharmaceuticals; GlaxoSmithKline; Bayer; Pharmacia; Sanofi-Aventis; Merck, maker of ertapenem; Elan, maker of cefepime; Chiron; Ortho-Biotech; Astra Zeneca; Oscient; Ortho-McNeil, maker of levofloxacin; Aerogen Pharmaceuticals; Abbott; Eli Lilly and Co, maker of vancomycin; and/or Bard Medical.

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Learning Objectives for This Educational Activity

Upon completion of this activity, participants will be able to:

- Describe the clinical diagnosis of HAP.
- Identify treatment options for HAP.

Clinical Context

Pneumonia is one of the most common complications of hospitalization, and its treatment can be complex. While physicians need to diagnose and treat HAP promptly, they must also be careful not to overuse antibiotics that can increase bacterial resistance. New data regarding the management of HAP, VAP, and HCAP has emerged since the 1996 set of guidelines proffered by the ATS, and the current guidelines reflect this latest evidence.

Study Highlights

- HAP was defined as pneumonia that occurs 48 hours or more after hospitalization, while VAP was defined to occur at 48 to 72 hours following intubation. HCAP was defined by admission to an acute care hospital for 2 of the previous 90 days, residence in a long-term care facility, or recent intravenous antibiotic therapy.
- The common etiologic agents causing nosocomial pneumonia include *P. aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*, and *Acinetobacter* species. Pneumonia with *S. aureus* is more common in patients with diabetes mellitus, head trauma, or intensive care unit admission.
- Patients with late-onset HAP are more likely to harbor MDR organisms, and their risk of mortality related to HAP is higher than those with early-onset disease.
- The most common pathogenesis of nosocomial pneumonia involves aspiration of oropharyngeal contents or leakage of secretions around the cuff of endotracheal tube.

- Intubation and mechanical ventilation increase the risk of HAP by 6- to 21-fold and should be avoided if possible.
- As supine position has been identified as a risk factor for VAP, especially during feeding, intubated patients should be kept in a semirecumbent position.
- Neither selective decontamination of the digestive tract nor prophylactic systemic antibiotics following intubation is recommended for routine use.
- All patients with suspected HAP should undergo sampling of secretions from the lower respiratory tract. Quantitative cultures of secretions offer better data on which to make treatment decisions than qualitative or semiquantitative cultures. A sterile culture of these secretions in the absence of the introduction of a new antibiotic during the previous 72 hours strongly suggests that bacterial pneumonia is not present. However, pneumonia related to viruses or *Legionella* remains possible in such patients.
- The most accurate clinical criteria for diagnosing HAP include the presence of a new infiltrate on chest radiography plus at least 2 of the following clinical features: fever, leukocytosis or leukopenia, or purulent secretions. Antibiotic therapy should be initiated promptly when these criteria are used, but the disadvantages to such a clinical model of diagnosis of HAP is the overuse of antibiotics.
- Selection of antibiotic treatment of nosocomial pneumonia depends on local patterns of disease, availability of antibiotics, and antibiotic resistance.
- In the absence of risk factors for MDR organisms such as prolonged hospitalization of more than 5 days, admission from a health care-related facility, or recent prolonged antibiotic therapy, initial therapy for HAP or VAP may be limited to one antibiotic. Ceftriaxone, a quinolone agent, ampicillin-sulbactam, or ertapenem may be used for this purpose.
- In all other patients, it is reasonable to initiate antibiotic therapy with a combination of the following agents:
 - an antipseudomonal cephalosporin or antipseudomonal carbapenem or β -lactam/ β -lactamase inhibitor plus
 - an antipseudomonal fluoroquinolone or aminoglycoside
- Linezolid or vancomycin may be used when infection with methicillin-resistant *S. aureus* is suspected.
- Most patients with nosocomial pneumonia respond to therapy within 3 days, and treatment duration may be held to 7 days, instead of the traditional 14 to 21 days, in patients who respond well.

Brief Combicath Literature Summary

A Summary of Relevant Studies Espousing the Use of Deep Lung Sampling in Determining the Proper Antibiotic Treatment for VAP

| Study or Paper | Summary |
|---|---|
| Fagon, et al., <u>Annals of Internal Medicine</u> , April 2000. | <ul style="list-style-type: none"> • Though this did not use the Combicath, it demonstrates the unreliability of Endotracheal Aspirates by comparing non-invasive sampling (EAs) to invasive sampling (bronchoscopic BAL). • False positive rate associated with Endotracheal Aspirates was 49%. • The invasive group had “significantly more antibiotic free days and fewer antibiotics per day”. |
| Campbell, et al. (Poster Presentation) | <ul style="list-style-type: none"> • In 114 patients, 96% of the Gram Stains correlated with the treatment chosen in the Quantitative Culture; thus, only 4% of patients did not respond to protocol. • Entire procedure took 8-10 minutes from set-up to clean up. • There were no significant complications, demonstrating the Combicath to be safe and effective. |
| Casetta, et al. <u>Chest</u> , June, 1999. | <ul style="list-style-type: none"> • Combicath (using dry aspiration) agreed with Bronchoscopic BAL 87% of the cases. • Despite this excellent comparison, the Combicath may have performed even better outside the scope of the study. • Three patients had left/upper lung infiltrates; obviously they were not prime candidates for the Combicath – a sampling device that usually goes into the right, lower lung. |
| Pham, Brun-Buisson, et al., <u>Am Rev Respir Dis</u> , 1991 | <ul style="list-style-type: none"> • “The PTC (Combicath) is at least as accurate as PSB (samples taken via bronchoscopy)... and it can result in substantial cost savings.” |
| Labenne, et al., <u>Critical Care Medicine</u> , 1999. | <ul style="list-style-type: none"> • Again, despite excellent outcomes of sensitivity (79%) and specificity (88%), this article states that specificity would have been 93% if the 7 contaminated samples hadn’t been counted. • Combicath contamination rate was much lower - 6% vs. 62% of Endotracheal Aspirates. • Combicath is safe and effective for most of the pediatric patient population. |
| Gauvin, et al., <u>American Journal of Respiratory and Critical Care Medicine</u> , 2002. | <ul style="list-style-type: none"> • 14 out of 30 symptomatic patients did not culture any organisms; thus did not need antibiotics. (consistent with Fagon, Labenne) • Reproducibility demonstrated using multiple inserters and multiple readers of the Combicath suggests a consistency in using the catheter. • Complications were mostly benign and transitory |
| Ost, et al., <u>American Journal of Critical Care Medicine</u> , 2003. | <ul style="list-style-type: none"> • This Decision Analysis study analyzes the Combicath and finds that the ability to adjust or scale back empiric antibiotic therapy after receiving quantitative culture results is the most cost effective method of prescribing antibiotics for VAP patients. • Using the Combicath to “back down” the empiric antibiotic therapy upon quantitative culture results was the lowest mortality group as well as the most cost effective. • Using the Combicath in this manner will also no doubt decrease the chance for antibiotic resistance. |



Use of the Gram Stain from Non-Bronchoscopic, Protected, Bronchoalveolar Lavage (NB-PAL) to guide empiric antibiotic therapy for suspected Ventilator-Associated Pneumonia (VAP).

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INTRODUCTION

Diagnosis of VAP is difficult and evidence supports quantitative bacteriology of BAL fluid as a sensitive and specific diagnostic technique. Potential advantages of NB-PAL are: collection of specimens by bedside staff, specimen collection prior to initiating antibiotic therapy (ABT), reduction in # of inadequate or contaminated specimens, and more appropriate selection of initial empiric ABT. We assessed the utility of the initial Gram Stain (GS) in guiding empiric ABT and its sensitivity and specificity for diagnosing VAP.

METHODS

NB-PAL specimens were obtained in 114 SICU patients meeting clinical criteria for VAP (WBC > 10,000, T > 38.5 C, purulent sputum, CXR infiltrate) for a six-month period (Oct 2000-Apr 2001). NB-PAL specimens were obtained by respiratory care practitioners using an 8 fr plugged, telescoping catheter (CombiCath™, PlastiMed). A 20 ml lavage volume was used. Specimens were excluded: for presence of squamous epithelial cells or if patients received > 24 hr of ABT. GS results were compared to the final quantitative culture (Cx) (positive Cx $\geq 10^4$ cfu/ml) to determine sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the GS. We recorded aspirated lavage volume, GS results, # of inadequate specimens, final Cx results, appropriateness of initial empiric ABT, and any complications (SpO₂ < 92%, 10% Δ in HR or BP sustained > 5 min, bleeding, pneumothorax, etc.) observed during the NB-PAL procedure.

The views expressed in this poster are those of the author and do not reflect the official policy or position of the United States Air Force, Department of Defense, or U.S. Government.

RESULTS

| Table 1. | Cx Result | | | |
|----------|-----------|----|----------|------------|
| | G+ | G- | G+ G- | No Grow |
| GS Morph | | | | |
| G+ | 10 | 0 | 0 | 1 |
| G- | 0 | 16 | 0 | 1 |
| G+/G- | 2 | 3 | 1 | 1 |
| No org | 0 | 4 | 0 | 50 |

114 patients were studied of which 25 were excluded. Eighty nine specimens were used for analysis. A final diagnosis of VAP was established in 36 (40%) patients. The correlation of GS and final quantitative Cx results are depicted in Table 1. "G+" = gram positive bacteria; "G-" = gram negative bacteria.

Lavage volume aspirated with NB-PAL was 2.1 ± 0.6 ml. Four (3.8%) of the NB-PAL specimens were inadequate due to presence of epithelial cells, 21 (18%) were excluded due to > 24 hours of ABT, and all specimens were > 1 ml. Of the remaining 89 specimens, 36 (40%) were positive for VAP (organisms > 10^4 cfu/ml on final Cx) and 42 (47%) negative for VAP (no growth on final Cx). The remaining 11 (13%) specimens were indeterminate (10^1 - 10^3 cfu/ml on final Cx).

Gram stain results were correlated with the final Cx result in 77 cases, partially correlated in 5 cases, and not correlated in 7 cases. When comparing the final diagnosis with the presence or absence of bacteria on GS, the sensitivity and specificity were 90% and 95%, respectively. The predictive value of a positive GS was 92% and the predictive value of a negative GS was 93%. Initial ABT based on GS was appropriate in 96% of cases. No episodes of hypoxemia were reported, as pts were ventilated with FiO₂ of 1.0 prior to and during the procedure. Minor bleeding was reported in 9 patients and significant hemodynamic changes were reported in 4 cases and all were resolved without clinical sequelae. Duration of the procedure was < 10 minutes in all cases.

DISCUSSION/CONCLUSION

Our results support the practice of initiating or withholding ABT based on the GS result obtained from NB-PAL. Further, selection of the components of empiric ABT based on GS appears appropriate. Outcome studies using GS as guide to ABT are recommended.

NB-PAL specimen collection by RCPs can be performed safely and quickly. The NB-PAL procedure is well tolerated, and yields an acceptable specimen for microbiological analysis in over 95% of cases. Use of a polyethylene glycol plug at the tip of the catheter may reduce the number of inadequate or contaminated specimens. Gram stain results from NB-PAL specimens strongly correlate with final Cx result and may be used to guide initial empiric antibiotic therapy. NB-PAL specimens are useful diagnostic tools that aid in the diagnosis of VAP in nearly 90% of our Surgical ICU pts with suspected VAP.

University of San Francisco Protocol Using Combicath Guidelines for Management of Ventilator-Associated Pneumonia

After 48 hours of mechanical ventilation:

Presence of a new or persistent lung opacity
On CXR plus at least 2 of the following:

1. Fever >38.3° C
2. Hypothermia < 36° C
3. WBC > 10,000/mm³ or < 5,000 mm³

Clinical Suspicion of VAP

OBTAIN Mini-BAL

(Can only obtain in intubated or patients with tracheostomies)

EXCLUSIONS:

- *Patients receiving 80% or higher FIO₂ and/or on 12 of PEEP
- *Patients who are hemodynamically unstable (as per ICU attending/fellows)
- *Patients who have severe obstructive lung disease or extremely high peak airway pressures

If NO previous antibiotic therapy:

1. Vancomycin + ceftriaxone
- OR**
2. Vancomycin + piperacillin/tazobactam (Zosyn)
 3. Vancomycin + fluorquinolone[¥]

X 48-72 hours

If previous antibiotic therapy:

1. Vancomycin + anti-pseudomonal β-lactam[§] + aminoglycoside[¶]
- OR**
2. Vancomycin + anti-pseudomonal β-lactam[§] + ciprofloxacin

X 48-72 hours

- If Mini BAL is compatible with the microbiologic diagnosis of VAP modify antibiotic therapy to organism(s) isolated
- If Mini BAL is not compatible with the microbiologic diagnosis of VAP and no other source of infection found, discontinue antibiotics
- If other source of infection found, narrow coverage to microbiologically confirmed pathogens

Significant ventilator associated pneumonia requiring therapy is associated with quantitative cultures of

≥ 10⁴ organisms/mL

Duration of antibiotic therapy should be 7 days unless the patient has *Pseudomonas*, *Acinetobacter* or *Stenotrophomonas*; for these pathogens duration of therapy should be 14 days.

Please consult the [adult antimicrobial dosing guidelines](#) or [ID pharmacy](#) for doses

¥ ciprofloxacin or levofloxacin

§ cefepime or Zosyn or ceftazidime or aztreonam

¶ tobramycin or gentamicin

Applicable Age-Groups

- | | | |
|---|---|---|
| <input type="checkbox"/> All age groups | <input checked="" type="checkbox"/> Geriatric | <input checked="" type="checkbox"/> Adult |
| <input type="checkbox"/> Adolescent | <input type="checkbox"/> Pediatric | <input type="checkbox"/> Neonate |

Body Substance Exposure Risk

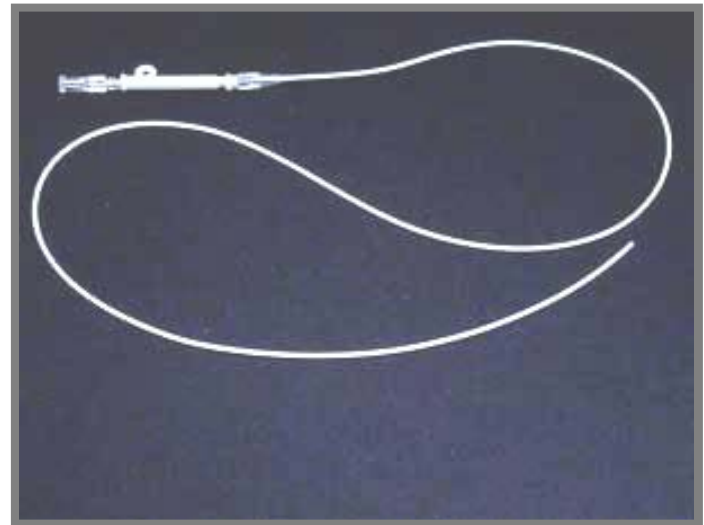
- Category I: Task involves exposure to blood, fluids or tissue
- Category II: Usual task does not involve exposure to blood, body fluid, or tissue, but may require performing unplanned Category I tasks.
- Category III: Task involves no exposure to blood, body fluids, or tissues.

**Non-bronchoscopic Bronchial Alveolar Lavage
(nBAL) using CombiCath™**

Introduction

The CombiCath™ is a protected, non-bronchoscopic catheter useful as a surveillance tool for identifying ventilator-associated pneumonia (VAP) particularly in critically ill patients. Studies on the use of non-directional sampling of lower airway secretions in mechanically ventilated patients have shown accurate results similar to that done via bronchoscopy. The non-bronchoscopic bronchoalveolar lavage (nBAL), or miniBAL is a minimally invasive technique using the CombiCath™ to sample from a subsegment of the lower airway while avoiding upper airway contamination.

Compared to sputum specimen (tracheal aspirates) obtained by ETT suction, the nBAL is more accurate in predicting lung infection versus airway colonization. Eliminating upper airway contamination from the specimen improves specificity and allowing early orientation of antibiotic therapy. The nBAL technique will increase the specificity of the diagnosis and to decrease antibiotic resistance of empiric therapy.

**Purpose**

To obtain distal lung fluid specimen for diagnosis of ventilator-associated pneumonia (VAP), using a protected double lumen catheter to prevent contamination of specimen with upper airway secretions.

Policy

RCS staff who completes in-service training/ orientation, demonstrates hands-on practice, and completes competency supervised by an adult clinical coordinator in the nBAL technique are authorized to perform the nBAL procedures. All respiratory therapist working in the adult critical care units are required to maintain competency in this technique so they can perform nBAL as ordered. Criteria to maintain competency include:

- Attending inservice or viewing the CD-ROM on CombiCath.
- Review RCS policy nBAL using CombiCath.
- Submit a completed competency assessment checklist.
- Observe at least one nBAL procedure.
- Assist with at least one nBAL procedure

- f. Perform at least one nBAL procedure under supervision.

The Respiratory Care Practitioner trained in the nBAL technique is responsible for obtaining the nBAL specimen on every intubated and ventilated patient in all adult intensive care areas upon the orders of a physician. A quantitative analysis will be performed by the microbiology laboratory.

Relative Contraindications and Notification of ICU Team Required

1. FiO2 \geq 0.90 and / or PEEP \geq 14cmH2O
2. Open External Ventricular Device (EVD) and / or ICP > 15 – 20. If a patient has an EVD a critical care fellow should be at the bedside for the nBAL procedure.
3. Severe COPD.
4. Unstable hemodynamics status and/ or dysrhythmias.
5. Scheduled bronchoscopy.

The RCP shall notify the ICU Team when nBAL is contraindicated as listed above. The Team should consider whether the relative contraindications warrants forgoing nBAL, tracheal aspirate instead, or other alternatives.

Precautions / Possible Complications

| | |
|---|--|
| <ol style="list-style-type: none"> 1) Bradycardia 2) Bronchospasm 3) Gagging / Vomiting 4) Bleeding | <ol style="list-style-type: none"> 5) Pneumothorax 6) Hypotension 7) Hypertension |
|---|--|

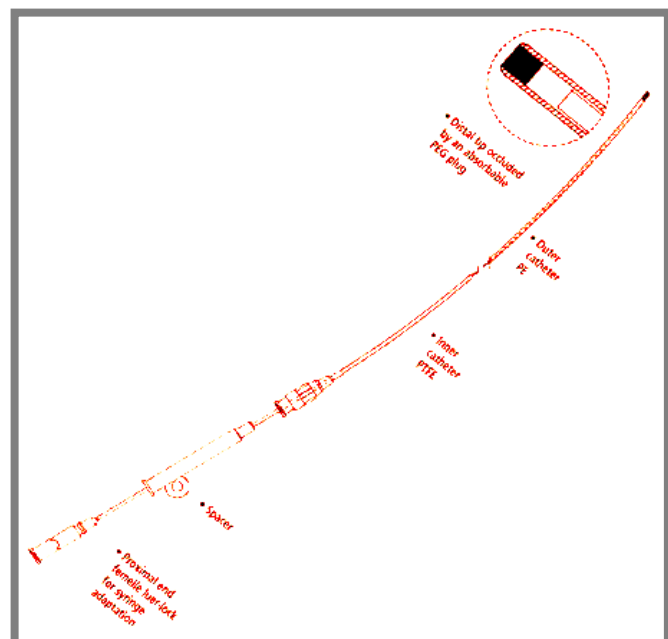
Supplies

| | |
|--|--|
| <ol style="list-style-type: none"> 1. CombiCath catheter (13 French OD) 58216.27 2. Sterile lubricating jelly 58223.19 3. One pair of sterile gloves pediatrics 4. One pair of non-sterile gloves 5. 100mL bag of sterile 0.9% Sodium Chloride 6. One blue pad | <ol style="list-style-type: none"> 7. One sterile screw top specimen container 8. Three 20 mL size syringe with luer-lok tip. 9. One spike 10. One Bodai suction safe airway adapter 11. One microbiology laboratory requisition 12. One suction kit |
|--|--|

Procedure

One person can perform n-BAL technique, but a second person is helpful.

1. Before beginning the procedure
 - a. Confirm physician order, look for contraindications, and review the need for nBAL. If serial monitoring is needed, nBAL should be performed 72 hours apart.
 - b. Gather necessary equipment or obtain a nBAL kit from the RCS dept.
 - c. Assess for relative contraindication.
 - d. Notify the ICU Team as required.
 - e. Assess for the need of bronchodilator treatment.



2. Prepare patient for the procedure
 - f. Pre-oxygenation with elevated F_iO₂. (F_iO₂ of 1.0) and suction using standard technique.
 - g. Replace the elbow adapter with the Bodai suction safe airway adapter.
 - h. Assure patient is adequately sedated to allay anxiety (minimal sedation)¹
 - i. Prepare the patient for the nBAL procedure; explain procedure to patient or family member as needed.
3. Prepare equipment and supplies
 - j. Drape the blue pad.
 - k. Using aseptic technique prepare 3 syringes (20 mL each) with up to 60 mL of non-bacteriostatic normal saline.
4. Perform nBAL procedure
 - a. Open the CombiCath package and lay catheter (still in protective sheath) on the blue pad.
 - b. Don sterile gloves
 - c. Advance the CombiCath catheter out of the protective sheath at the open end (end with red plug) and introduce catheter into the artificial airway through the bronchoscopy adapter. **DO NOT ATTEMPT TO REMOVE RED PLUG** (this plug is absorbable in the lung)
 - d. Gently advance the catheter until resistance is met, indicating the catheter is "wedged" into the distal airway.
 - e. Pull the catheter out approximately 3-4 cm to allow room for the inner catheter to be advanced.
 - f. Remove the white plastic protective spacer that separates the inner and outer catheters.
 - g. Gently advance the inner catheter and connect it to the outer catheter by slightly twisting it into the outer connector.
 - NOTE * Advancing the inner catheter will dislodge the absorbable polyethylene glycol plug at the distal end of the catheter.
 - h. Connect a 20-ml syringe to the catheter and briskly administer all of the normal saline.
 - NOTE * Extreme backpressure sensed during the lavage may indicate kinking of the catheter, occlusion of the distal end by sputum or tissue and may require slight position adjustment to allow smooth flow through the catheter.
 - i. Aspirate lavage sample using the same 20-ml syringe while maintaining catheter position
 - NOTE * Extreme backpressure during the aspiration stage may indicate the distal end is occluded with thick sputum or the end may be directed into the sidewall of the airway. Slowly rotate the catheter while aspirating to enhance aspiration of lavage fluid. Do not disconnect the syringe if air is aspirated into the syringe. Simply hold the syringe in the upright position and push the air back through the catheter while keeping any aspirated lavage fluid in the syringe. Repeat the aspiration process as necessary until an appropriate specimen is obtained (a minimum of 1.0 ml is required for proper laboratory analysis).
 - j. If thick sputum is likely prohibiting proper aspiration, the inner catheter may be removed and aspiration may be attempted through the outer catheter.
 - k. Remove the CombiCath from the airway the syringe still attached.
 - l. Place the sample into the specimen container being very careful not to cause any contact contamination.
 - m. Tightly secure the lid on the specimen container.
5. After the nBAL procedure
 - a. Assess patient's oxygenation status and return to the previous oxygen settings on the ventilator as indicated.
 - b. Assess bilateral breath sounds.

- c. Suction the patient (if indicated) using standard technique to remove excess lavage fluid
- d. Place patient label on the specimen container & indicate write in the unit and the bed number.
- e. Complete microbiology requisition form for complete quantitative analysis and indicate source as nBAL specimen.
- f. Discard equipment per hospital policy and procedure.
- g. Forward specimen to lab per hospital policy and procedure.
- h. Chart "nBAL x1" in the department master.
- i. Chart "nBAL procedure, FiO2/SpO2, BS, how procedure tolerated" on the Critical Care Flowsheet.
- j. Expect results from nBAL procedure 24 to 48 hours.

References – Copies of references available in the RCS Department Room M069

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