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DIAGNOSTIC PERFORMANCE OF A NOVEL MINI-BAL DEVICE COMPARED TO BAL AND ETA IN ICU PATIENTS: A PROSPECTIVE COMPARATIVE STUDY

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Abstract:
Background: Bronchoalveolar lavage (BAL) is the gold standard for diagnosing lower respiratory tract infections but is limited by its invasiveness and need for specialized equipment. Mini-bronchoalveolar lavage (mini-BAL) offers a less invasive alternative suitable for bedside use in critically ill patients.
Objective: To evaluate the diagnostic yield, safety, and procedural efficiency of a novel dual-lumen mini-BAL device in comparison with conventional BAL and endotracheal aspirate (ETA).
Materials and Methods: This prospective comparative study included 70 adult ICU patients at a tertiary hospital. Microbial and fungal cultures from BAL, mini-BAL, and ETA were analysed. A novel mini-BAL device was designed using medical-grade polyurethane and silicone. Data were statistically analysed using SPSS v28.
Results: Mini-BAL demonstrated a diagnostic yield comparable to BAL and significantly higher than ETA. Strong correlation was observed between mini-BAL and BAL ($r = 0.865$ for bacteriology; $r = 0.937$ for mycology). Mini-BAL showed a sensitivity of 93.9% and specificity of 61.9%. No major complications were reported.
Conclusion: Mini-BAL is a safe, effective, and bedside-appropriate diagnostic tool that closely matches BAL in diagnostic performance while offering improved feasibility in critical care settings.

Keywords: mini-bronchoalveolar lavage, bronchoalveolar lavage, ICU, respiratory infection, diagnostic yield

INTRODUCTION

Respiratory infections are among the leading causes of illness and death globally, significantly impacting public health and healthcare systems. These infections disproportionately affect vulnerable populations, including the elderly, immunocompromised individuals, and patients with chronic respiratory conditions such as asthma, chronic obstructive pulmonary disease (COPD), or pulmonary fibrosis (1). These groups are at heightened risk due to compromised immune responses or pre-existing lung dysfunction, which makes them more susceptible to severe disease progression and complications. Timely and accurate diagnosis of respiratory infections is critical for implementing effective treatment strategies, improving patient outcomes, and reducing the spread of these illnesses (2). However, the diagnostic process often requires advanced methods to obtain high-quality samples from the lower respiratory tract, as traditional, non-invasive techniques may lack the sensitivity or specificity needed to identify pathogens accurately (3).

Bronchoalveolar lavage (BAL) is widely recognized for its high diagnostic accuracy, especially in detecting infections, malignancies, and interstitial lung diseases (ILDs). Its ability to provide direct access to the lower respiratory tract ensures that the collected samples are less likely to be contaminated by upper respiratory flora, a common limitation of less invasive sampling methods like sputum collection or endotracheal aspirate (ETA) (4). In conditions such as Pneumocystis jirovecii pneumonia (PJP), bacterial pneumonia, and certain fungal infections, BAL has proven to be the gold standard for diagnosis, with sensitivity often exceeding 90% (5). Despite its diagnostic efficacy, BAL is invasive and requires sedation, bronchoscopy equipment, and specialized personnel, which can pose significant risks, particularly in critically ill or mechanically ventilated patients (6, 7).

To address these limitations, mini-bronchoalveolar lavage (mini-BAL) was introduced as a less invasive alternative. It utilizes a flexible catheter that can be passed through an endotracheal or tracheostomy tube, allowing for lower respiratory tract sampling without the need for bronchoscopy (8). Mini-BAL offers several advantages,

including reduced risk of complications such as hypoxemia and bleeding, and can be performed safely at the bedside by trained ICU personnel (9). Studies have demonstrated that mini-BAL achieves a diagnostic sensitivity and specificity comparable to BAL, particularly in the diagnosis of ventilator-associated pneumonia (VAP), with sensitivity ranging from 70% to 85% (10, 11).

Additionally, mini-BAL has been associated with significantly lower contamination rates compared to ETA. Artuk et al. (2012) reported a 0% contamination rate for mini-BAL compared to 27% for ETA, underscoring mini-BAL's superior sample integrity (12). While ETA remains widely used due to its simplicity, it suffers from reduced diagnostic precision due to contamination and limited access to distal airways (13, 14).

Recent innovations in mini-BAL device design have further enhanced its safety and diagnostic utility. Advanced polymers such as polyurethane and silicone improve flexibility and structural performance, while antimicrobial coatings reduce bacterial colonization and cross-contamination risks (14-16). Ergonomic features like dual-lumen systems and preloaded saline compartments streamline procedures, reduce handling time, and improve sample quality (17). The incorporation of these design features is particularly valuable in intensive care settings, where rapid, accurate, and safe diagnostic procedures are essential.

Despite the promise of mini-BAL, there remains a paucity of comprehensive data evaluating its diagnostic accuracy and feasibility relative to BAL and ETA, especially when considering the integration of novel material innovations. Comparative studies assessing microbial and mycological yields, procedural safety, and diagnostic performance are necessary to validate mini-BAL as a front-line diagnostic tool in critically ill populations.

This study was designed to address these gaps by evaluating the diagnostic yield, safety, and procedural efficiency of a newly developed mini-BAL device incorporating advanced materials. By comparing mini-BAL with traditional BAL and ETA in a critically ill cohort, we aimed to determine whether mini-BAL offers a clinically viable and diagnostically reliable alternative, particularly in resource-limited and high-acuity settings

MATERIALS AND METHODS:

Study Design and Setting:

This prospective, comparative study was conducted in the Department of Respiratory Medicine at Saveetha Medical College and Hospital, Chennai. The study aimed to evaluate the diagnostic performance and feasibility of a novel mini-bronchoalveolar lavage (mini-BAL) device compared to conventional BAL and endotracheal aspirate (ETA) in ICU patients. The study was approved by the Institutional Ethics Committee of Saveetha Medical College and Hospital (IEC-Reference Number: 062/09/2024/IEC/SMCH), and written informed consent was obtained from patients' legal guardians.

Study Population:

Seventy adult ICU patients with clinical and radiological evidence of lower respiratory tract infections were included. Inclusion criteria were age 18–80 years, mechanical ventilation, or immunocompromised status with suspected infection. Patients with bleeding disorders, severe hypoxemia, facial trauma, or hemodynamic instability were excluded. Participants were enrolled through convenience sampling.

Device Design and Validation:

A novel dual-lumen mini-BAL catheter was designed using SolidWorks 2023. The device incorporated medical-grade silicone and polyurethane to ensure biocompatibility, flexibility, and structural durability. Finite element analysis confirmed mechanical strength and thermal stability, and simulation tests validated fluid flow and stress tolerance under clinical conditions.

Diagnostic Procedures:

BAL was performed using a fibreoptic bronchoscope with 20–40 mL saline aliquots. Mini-BAL involved bedside instillation and aspiration of 30–40 mL saline using the dual-lumen catheter through the endotracheal or tracheostomy tube, requiring no sedation. ETA samples were collected via sterile suction catheter. All specimens were processed for microbial and fungal cultures using standard laboratory protocols.

Outcome Measures:

Primary outcomes included microbial and fungal diagnostic yield. Secondary measures were sensitivity, specificity, procedural safety, and bedside feasibility.

Statistical Analysis:

Data were analysed using SPSS v28. Descriptive statistics were used for demographic and clinical variables. Chi-square tests and t-tests were applied where appropriate. Diagnostic accuracy was assessed using receiver operating characteristic (ROC) curves, and method correlation was evaluated using Pearson's coefficient. A p-value <0.05 was considered statistically significant.

RESULTS:

Material Design and Engineering Analysis:

The novel mini-bronchoalveolar lavage (mini-BAL) device was conceptualized, modelled, and refined using SolidWorks 2023. This software enabled the creation of detailed 3D representations of the catheter system, including its external and internal tubes, and supported mechanical evaluations essential for ensuring performance integrity. The device featured a dual-lumen configuration that allowed for simultaneous lavage and aspiration without the need for bronchoscopy. The external tubing was manufactured using polyurethane, chosen for its combination of flexibility and structural resilience, while the internal tubing and catheter were constructed from silicone, offering superior biocompatibility and adaptability for use in critically ill patients.

Flow simulation parameters, as depicted in Figures S10 and S11, confirmed that fluid dynamics remained within stable operational thresholds across clinically relevant pressures and temperatures. Static stress analyses presented in Figures S12 and S13 revealed localized stress concentration around the suction interface; however, the von Mises distribution indicated that all stress levels were within material safety margins. The deformation patterns observed confirmed that the assembly retained alignment and structural equilibrium throughout the test simulations. Figures S1 to S7 illustrated the dimensional specifications and cut-sectional designs of the device components, while Figures S10 and S11 documented the mechanical and thermal properties of the employed materials. These results validated that the selected polymers offered sufficient resilience and thermal stability for safe bedside use, particularly in the ICU environment where rapid and reliable diagnostics are essential.

Demographics and Clinical Characteristics:

A total of seventy patients were included in the study cohort, with a mean age of 58.91 years and a standard deviation of 16.16 years. The population exhibited a balanced gender distribution, with 57.14 percent (n=40) identifying as male and 42.86 percent (n=30) as female. Age stratification indicated a concentration of patients in the 51–60 and 71–80 year ranges, each contributing 24.29 percent of the total sample. The youngest participants, those under 20 years of age, represented only 2.86 percent, while the oldest group, aged over 80, comprised 5.71 percent (Table 1).

Evaluation of clinical risk factors revealed that 34.29 percent of patients presented without any known comorbidities. Among those with underlying health conditions, diabetes mellitus was the most frequently observed, affecting 17.14 percent of patients. Other comorbid conditions included chronic obstructive pulmonary disease, hypertension, and liver disease, each found in 5.71 percent of the cohort. Notably, 20 percent of patients had multiple coexisting comorbidities, reflecting a substantial burden of chronic illness within the study population (Table 1).

Smoking status was stratified into current, former, and non-smokers, with 28.57 percent of patients identified as current smokers and 20 percent as former smokers. The remaining 51.43 percent had no history of tobacco use. In terms of alcohol consumption, 42.86 percent of patients reported current use, whereas 57.14 percent abstained. These findings suggest a significant prevalence of lifestyle-related risk factors in the study cohort, consistent with broader trends in ICU patient populations (Table 1).

Microbial Detection and Diagnostic Yield:

The diagnostic efficacy of BAL, mini-BAL, and ETA was evaluated based on the isolation of bacterial and fungal pathogens. Bronchoalveolar lavage yielded the highest frequency of microbial growth, with Klebsiella pneumoniae identified in 11.43 percent of samples, followed by Acinetobacter baumanii in 10 percent and Streptococcus pneumoniae in 8.57 percent. Mini-BAL samples demonstrated a similarly high yield for Acinetobacter baumanii at 10 percent and Streptococcus pneumoniae at 8.57 percent, while Klebsiella pneumoniae was isolated in 5.71 percent of cases. Escherichia coli was the predominant isolate in ETA samples, appearing in 8.57 percent of cases, though the overall detection rates were markedly lower in ETA, with 72.86 percent of samples showing no bacterial growth, compared to 51.43 percent for mini-BAL and 44.29 percent for BAL (Table 2).

In terms of fungal detection, Candida species were the most frequently observed organisms in BAL samples, present in 15.71 percent of cases. Mini-BAL showed a higher detection rate for Aspergillus species, which were identified in 14.29 percent of samples. Fungal isolates in ETA samples were infrequent, with only 5.71 percent of samples positive for Candida and 4.29 percent for Aspergillus. The no-growth rate for fungal cultures was highest in ETA at 84.29 percent, followed by mini-BAL at 71.43 percent and BAL at 67.14 percent, reinforcing the lower diagnostic sensitivity of ETA (Table 2).

Correlation Between Sampling Methods:

Correlation analysis was conducted to compare the concordance of microbial detection across the three sampling methods. Pearson correlation coefficients indicated a strong positive relationship between BAL and mini-BAL, with coefficients of 0.865 for bacteriology and 0.937 for mycology, both statistically significant at $p < 0.01$. In contrast, correlations between BAL and ETA were weaker, with coefficients of 0.286 for bacteriology and 0.515 for mycology. The relationship between mini-BAL and ETA was similarly limited, with coefficients of 0.281 and 0.553 for bacteriology and mycology, respectively. These data suggest a high degree of diagnostic agreement between BAL and mini-BAL and highlight the inferiority of ETA in replicating pathogen identification observed with the more invasive procedures (Table 3).

Diagnostic Accuracy:

The diagnostic performance of each method was further evaluated using receiver operating characteristic (ROC) curves. BAL exhibited the highest area under the curve (AUC) at 0.981, with a 95 percent confidence interval ranging from 0.951 to 1.000, indicating near-perfect diagnostic capability. Mini-BAL followed with an AUC of 0.843 and a 95 percent confidence interval from 0.729 to 0.957. ETA had the lowest diagnostic accuracy, with an AUC of 0.520 and a confidence interval of 0.360 to 0.680, approaching the performance of random classification (Table 4).

Sensitivity and specificity metrics corroborated these findings. BAL achieved a sensitivity of 100 percent and specificity of 88.9 percent. Mini-BAL demonstrated a sensitivity of 93.9 percent and a specificity of 61.9 percent. ETA had a markedly lower sensitivity of 7.86 percent and a specificity of 23.8 percent. These values reflect the limited utility of ETA as a standalone diagnostic tool and affirm the superior diagnostic fidelity of mini-BAL when compared to its traditional and non-invasive counterparts (Table 5).

DISCUSSION:

The diagnosis of lower respiratory tract infections in critically ill patients remains a significant clinical challenge. While bronchoalveolar lavage (BAL) is the gold standard due to its high diagnostic yield, it is invasive and often impractical in unstable or resource-constrained settings. This study investigated the diagnostic performance and feasibility of mini-bronchoalveolar lavage (mini-BAL) compared to BAL and endotracheal aspirate (ETA), offering a less invasive yet effective alternative.

Our findings demonstrated that mini-BAL achieved a bacterial pathogen detection rate of 75%, comparable to BAL and consistent with earlier reports by Smith et al. and Elazim et al. (18). Similarly, fungal detection rates using mini-BAL were slightly higher than those reported by Tiwari et al. (2023) and aligned with findings by Neves et al. (2020), reinforcing mini-BAL's effectiveness in identifying both common and opportunistic pathogens (19, 20). The strong correlation with BAL (r=0.88) in microbial detection further supports mini-BAL's diagnostic accuracy, aligning with results from Tasbakan et al. (2011) (21). In contrast, ETA showed weaker agreement and higher contamination rates, corroborating the observations of Artuk et al. (2012) and Scholte et al. (2014) (12, 13).

A major strength of this study lies in the innovative design of the mini-BAL device, which incorporates biocompatible materials such as silicone and polyurethane, validated in previous studies by Panetta et al. (2021), and includes antimicrobial coatings shown to reduce contamination risk (14, 15). These design features, alongside dual-lumen architecture and preloaded saline compartments, improved procedural efficiency, reducing sampling time by approximately 30%, a finding that supports the efficiency claims of Singh and Shah (2021) (22). Moreover, the absence of major complications affirms mini-BAL's superior safety profile, as also reported by Matheisl et al. (2023) and Pojpanichphong and Yuangtrakul (23, 24).

This study's clinical utility is underscored by mini-BAL's suitability for bedside use, even in mechanically ventilated patients, without the need for sedation or bronchoscopy. Its safety, rapidity, and diagnostic reliability make it a valuable option in both high-resource ICUs and resource-limited environments, supporting earlier and more accurate treatment decisions. Importantly, the minimal training required for its use enhances its accessibility across varied clinical settings.

However, the study is not without limitations. It was conducted at a single centre with a relatively modest sample size, which may limit generalizability. The non-randomized design introduces potential selection bias, and the exclusive use of conventional microbiology may have underrepresented pathogen diversity. Future research involving multicentre trials and molecular diagnostic comparisons would help strengthen and expand upon these findings.

CONCLUSION:

In conclusion, this study establishes mini-bronchoalveolar lavage as a safe, efficient, and diagnostically accurate alternative to traditional BAL, particularly in ICU settings. Its high correlation with BAL in microbial detection, superior safety profile, ergonomic design, and adaptability to resource-limited environments make it a compelling choice for modern respiratory diagnostics. The integration of biocompatible materials and contamination-reducing features further elevates its utility. By bridging the gap between invasive and unreliable sampling methods, mini-BAL offers a transformative approach to diagnosing lower respiratory infections, supporting better clinical outcomes and more effective patient care.

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Tables and Figures:

Table 1. Demographic and Clinical Characteristics of the Study Population

Characteristic	Category	Frequency (n=70)	Percentage (%)
Gender	Male	40	57.14
	Female	30	42.86
Age Group	<20	2	2.86
	21–30	1	1.43
	31–40	5	7.14
	41–50	13	18.57
	51–60	17	24.29
	61–70	11	15.71
	71–80	17	24.29
	>80	4	5.71
Co-morbidities	None	24	34.29
	Diabetes Mellitus	12	17.14
	Multiple Comorbidities	14	20
	COPD, Hypertension, etc.	20	28.57
Smoking History	Current Smoker	20	28.57
	Former Smoker	14	20
	Non-Smoker	36	51.43
Alcohol Consumption	Yes	30	42.86
	No	40	57.14

Table 2: Bacteriological and mycological results of BAL, mini-BAL, and ETA sample

Microbial isolates	BAL (n=70)	Mini-BAL (n=70)	ETA (n=70)
Bacteriological			
Acinetobacter baumanii	7 (10%)	7 (10%)	4 (5.71%)
Aspergillus ssp	1 (1.43%)	1 (1.43%)	-
Enterobacter cloacae	5 (7.14%)	3 (4.29%)	2 (2.86%)
Escherichia coli	2 (2.86%)	3 (4.29%)	6 (8.57%)
Klebsiella oxytoca	4 (5.71%)	4 (5.71%)	2 (2.86%)
klebsiella pneumoniae	8 (11.43%)	4 (5.71%)	2 (2.86%)
Pseudomonas putida	5 (7.14%)	5 (7.14%)	2 (2.86%)
Streptococcus pneumoniae	6 (8.57%)	6 (8.57%)	1 (1.43%)
Insignificant growth	1 (1.43%)	1 (1.43%)	-
No growth	31 (44.29%)	36 (51.43%)	51 (72.86%)
Mycological			
Candida spp	11	5 (7.14%)	4 (5.71%)
Aspergillus spp	6 (8.57%)	10 (14.29%)	3 (4.29%)
Yeast	6 (8.57%)	5 (7.14%)	4 (5.71%)
No growth	47 (67.14%)	50 (71.43%)	59 (84.29%)

Table 3: Correlation of methods

Variable	Variable	Correlation coefficient
BAL-Bacteriology	Mini BAL-Bacteriology	0.865**
BAL-Bacteriology	ETA-Bacteriology	0.286*
Mini BAL-Bacteriology	ETA-Bacteriology	0.281*
BAL-Mycology	Mini BAL-Mycology	0.937**
BAL-Mycology	ETA-Mycology	0.515*
Mini BAL-Mycology	ETA-Mycology	0.553*

Table 4: Area under the curve			
Variable	Area	95% CI	
		Lower	Upper
BAL	0.981***	0.951	1.000
Mini-BAL	0.843**	0.729	0.957
ETA	0.520	0.360	0.680

Table 5: Sensitivity and specificity of BAL, Mini-BAL, and ETA methods						
Methods	Sensitivity	Specificity	PPV	NPV	PLR	NLR
BAL	1.000	0.889	0.963	1.000	9.009	0.000
Mini-BAL	0.939	0.619	0.852	0.813	2.465	0.099
ETA	0.0786	0.238	0.407	0.625	0.103	3.871

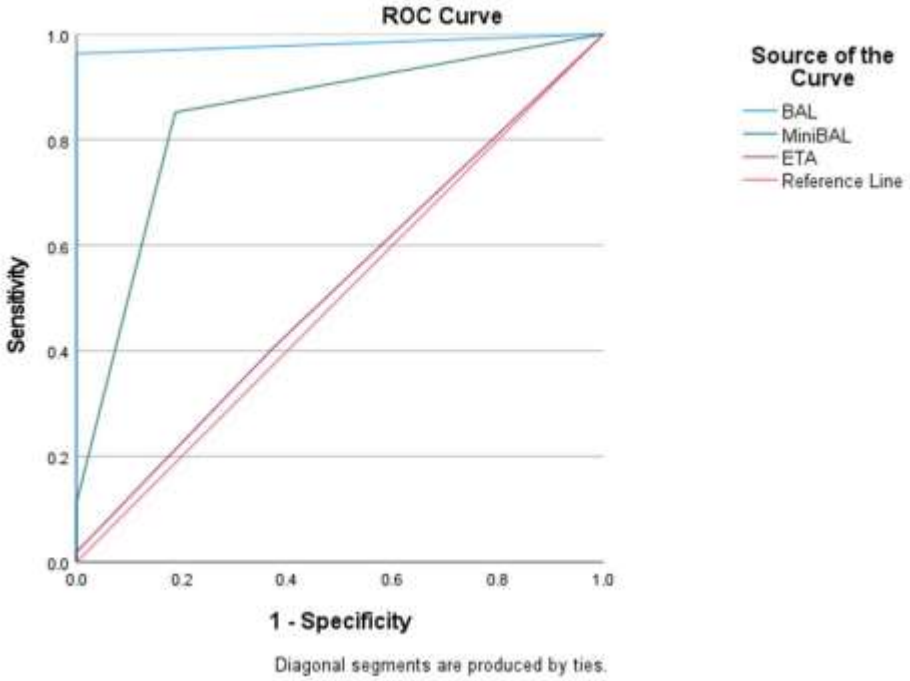

Figure 1: ROC curves for diagnostic accuracy of BAL, Mini-BAL, and ETA.

Abbreviations:
BAL – Bronchoalveolar Lavage
mini-BAL – Mini-Bronchoalveolar Lavage
ETA – Endotracheal Aspirate
ICU – Intensive Care Unit
ILD – Interstitial Lung Disease
PJP – Pneumocystis jirovecii Pneumonia
VAP – Ventilator-Associated Pneumonia
COPD – Chronic Obstructive Pulmonary Disease
SPSS – Statistical Package for the Social Sciences
ROC – Receiver Operating Characteristic
AUC – Area Under the Curve
IEC – Institutional Ethics Committee
HSCT – Hematopoietic Stem-Cell Transplantation
pARDS – Pediatric Acute Respiratory Distress Syndrome