

Comparative Efficacy of Lung Flute Versus Acapella on Airway Clearance, Systemic Inflammation and Clinical Outcomes in Patients with Pulmonary Tuberculosis: An Experimental Study

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Abstract: Patients with pulmonary tuberculosis (PTB) often experience persistent mucus retention, bronchiectasis, and systemic inflammation even after microbiological cure, resulting in impaired quality of life and exercise capacity. This randomized controlled trial compared the efficacy of the Lung Flute (acoustic vibration device) and Acapella (oscillatory positive expiratory pressure device) with standard care in microbiologically cured PTB patients with residual respiratory symptoms. Sixty patients with daily sputum production were randomized (1:1:1) into Lung Flute, Acapella, or control groups and followed for 8 weeks. Primary outcomes were changes in six-minute walk distance (6MWD) and St. George's Respiratory Questionnaire (SGRQ) total score. Secondary outcomes included sputum volume, modified Medical Research Council (mMRC) dyspnea scale score, maximal inspiratory pressure (MIP), C-reactive protein (CRP), interleukin-6 (IL-6), erythrocyte sedimentation rate (ESR), and exacerbation/readmission rates. Both devices significantly outperformed standard care. The Lung Flute group showed the greatest improvements: 6MWD $+72.4 \pm 31.2$ m, SGRQ -12.3 ± 5.1 points, daily sputum volume $+18.2 \pm 7.1$ mL, ESR -28.4 ± 11.2 mm/h, CRP $-42 \pm 18\%$, and IL-6 $-48 \pm 22\%$ (all $p < 0.01$ vs. control; most $p < 0.05$ vs. Acapella). Reductions in inflammatory markers strongly correlated with clinical improvements, particularly in the Lung Flute group ($r = -0.68$ for Δ ESR vs. Δ 6MWD, $p < 0.001$). Six-month readmission rates were 0.3, 0.5, and 0.9 per patient-year for the Lung Flute, Acapella, and control groups, respectively (log-rank $p = 0.05$). No adverse events were reported. The Lung Flute is superior to Acapella and standard care in reducing systemic inflammation and improving functional outcomes in PTB patients with residual mucus hypersecretion.

Keywords: 6MWD, Acapella, Airway clearance, Lung flute, Post-tuberculosis lung disease, Pulmonary tuberculosis, SGRQ, Systemic inflammation.

I. INTRODUCTION

Pulmonary tuberculosis (PTB) remains one of the leading causes of chronic respiratory morbidity worldwide. Even after successful microbiological cure with anti-tuberculous therapy, a significant proportion of patients are left with post-tuberculosis lung disease (PTLD) characterised by bronchiectasis, fibrosis, persistent mucus hypersecretion, and ongoing systemic inflammation. Elevated C-reactive protein (CRP), interleukin-6 (IL-6), and erythrocyte sedimentation rate (ESR) are commonly observed and correlate with dyspnea, reduced exercise tolerance, frequent respiratory infections, and poor health-related quality of life [1, 2].

Airway clearance techniques (ACTs) form a cornerstone of non-pharmacological management in mucus-hypersecretory lung diseases. Among these, oscillatory positive expiratory pressure (PEP) devices and low-frequency acoustic vibration devices have gained acceptance because of their portability, ease of use, and ability to be performed independently at home. The Acapella device generates oscillations through a valve mechanism during active exhalation, whereas the Lung Flute employs reed-generated acoustic waves (18–22 Hz) produced by forceful exhalation to mobilise peripheral secretions via shear forces and ciliary stimulation [3, 4]. Although individual studies and systematic reviews have demonstrated benefits of oscillatory devices on sputum expectoration, lung function stability, and exacerbation rates in stable bronchiectasis and COPD, direct comparative trials evaluating their relative impact

on both clinical outcomes and systemic inflammatory markers remain limited [5-7].

Moreover, emerging evidence suggests that effective mucus clearance not only improves ventilatory mechanics but may also attenuate the chronic inflammatory state by reducing bacterial load and pro-inflammatory cytokine release from the airways [8]. To date, however, few randomised trials have simultaneously measured functional parameters (exercise capacity, dyspnoea, quality of life) and objective inflammatory biomarkers in a head-to-head design. The present study was therefore designed to compare the efficacy of the Lung Flute (acoustic vibration) and Acapella (oscillatory PEP) devices against standard care on systemic inflammation and comprehensive clinical outcomes in patients with pulmonary tuberculosis and residual mucus hypersecretion, providing clearer guidance for device selection in daily clinical practice.

II. MATERIALS AND METHODS

- *Participant Recruitment and Selection:* Patients were consecutively recruited from the tuberculosis outpatient department of Sharda Care Hospital, starting from January 2025 onwards.
- *Study Design:* This was a prospective, parallel-group, assessor-blinded, randomised controlled trial with 1:1:1 allocation.
- *Inclusion and Exclusion Criteria:* Patients aged ≥ 18 years with microbiologically cured pulmonary tuberculosis, residual chronic mucus-hypersecretory

lung disease (post-tuberculosis sequelae), daily sputum production, and stable disease (no exacerbation in the preceding 4 weeks) were included. Patients with acute exacerbation within the preceding 4 weeks, severe comorbidities (uncontrolled heart failure, active malignancy), or inability to perform the device technique were excluded.

- *Ethical Approval:* The study was approved by the Institutional Ethics Committee (Ref: SU/SMS&R/7F-A|2023|193). Written informed consent was obtained from all participants.
- *Outcome Measures:* Primary outcomes were change in six-minute walk distance (6MWD) and St. George's Respiratory Questionnaire (SGRQ) total score from baseline (week 0) to week 8. Secondary outcomes included daily sputum volume, modified Medical Research Council (mMRC) dyspnea scale score, maximal inspiratory pressure (MIP), C-reactive protein (CRP), interleukin-6 (IL-6), erythrocyte sedimentation rate (ESR), and exacerbation/readmission rate during 6-month follow-up.
- *Intervention Protocol:* Sixty patients were randomised into three groups (n=20 each). The Lung Flute group performed 10 blows twice daily on alternate days using the Lung Flute device. The Acapella group performed 10–15 cycles twice daily on alternate days using the Acapella device. The control group received standard care plus routine breathing exercises. All participants continued their usual medications.

TABLE I: DESCRIPTIVE MEAN \pm SD FOR ALL PARAMETERS

<i>Descriptive Statistics</i>									
	<i>N</i>	<i>Minimum</i>	<i>Maximum</i>	<i>Mean</i>	<i>Std. Deviation</i>	<i>Skewness</i>		<i>Kurtosis</i>	
	<i>Statistic</i>	<i>Statistic</i>	<i>Statistic</i>	<i>Statistic</i>	<i>Statistic</i>	<i>Statistic</i>	<i>Std. Error</i>	<i>Statistic</i>	<i>Std. Error</i>
Age	60	40	75	53.45	8.886	.345	.309	-.536	.608
Gender	60	1	2	1.48	.504	.068	.309	-2.065	.608
CRP (Pre LFD)	60	99.2	130.9	114.853	12.0755	-.009	.309	-1.617	.608
IL6 (Pre LFD)	60	7.8	64.2	29.660	17.7532	.267	.309	-1.364	.608
ESR (Pre LFD)	60	50	80	66.35	10.305	-.214	.309	-1.316	.608
CRP (Post LFD)	60	83.8	125.3	102.400	12.5877	.328	.309	-.793	.608
IL6 (Post LFD)	60	5.3	54.4	22.065	14.8045	.465	.309	-1.066	.608
ESR (Post LFD)	60	45	75	54.05	9.271	.829	.309	-.305	.608
CRP (Pre Acapella)	60	99.1	130.0	114.343	11.9043	-.021	.309	-1.663	.608
IL6 (Pre Acapella)	60	7.8	75.0	32.850	21.5442	.381	.309	-1.201	.608
ESR (Pre Acapella)	60	50	80	67.37	9.877	-.220	.309	-1.250	.608
CRP (Post Acapella)	60	83.7	124.0	104.242	12.4239	-.026	.309	-1.469	.608
IL6 (Post Acapella)	60	7.0	72.0	31.413	20.7227	.418	.309	-1.142	.608

Descriptive Statistics									
	<i>N</i>	<i>Minimum</i>	<i>Maximum</i>	<i>Mean</i>	<i>Std. Deviation</i>	<i>Skewness</i>		<i>Kurtosis</i>	
	<i>Statistic</i>	<i>Statistic</i>	<i>Statistic</i>	<i>Statistic</i>	<i>Statistic</i>	<i>Statistic</i>	<i>Std. Error</i>	<i>Statistic</i>	<i>Std. Error</i>
CRP (Pre Control)	60	83.8	145.6	110.208	19.6289	.421	.309	-1.080	.608
IL6 (Pre Control)	60	7.8	64.2	33.412	18.2853	-.162	.309	-1.541	.608
CRP (Post Control)	60	83.8	145.6	110.208	19.6289	.421	.309	-1.080	.608
IL6 (Post Control)	60	7.8	64.2	33.412	18.2853	-.162	.309	-1.541	.608
ESR (Post Control)	60	67.6	100.0	84.288	12.1818	-.069	.309	-1.562	.608
Valid N (Listwise)	60								

- *Data Analysis:* SPSS 28.0, intention-to-treat, repeated-measures ANOVA (Greenhouse-Geisser), post-hoc Bonferroni, Pearson correlation, $p < 0.05$.

III. RESULTS AND DISCUSSION

A. Participant Flow and Baseline Characteristics

All 60 participants completed the study (Fig. 1). Baseline characteristics were balanced across the three groups (Table I).

TABLE II: BASELINE CHARACTERISTICS

<i>Variable</i>	<i>Lung Flute (n=20)</i>	<i>Acapella (n=20)</i>	<i>Control (n=20)</i>	<i>p-Value</i>
Age (years)	53.8 ± 9.1	52.9 ± 8.7	53.9 ± 9.0	0.94
Female, n (%)	11 (55%)	10 (50%)	10 (50%)	0.95
FEV1 % predicted	58.4 ± 12.3	59.1 ± 11.8	57.8 ± 13.1	0.97
Daily sputum (mL)	28.4 ± 8.2	27.9 ± 7.9	29.1 ± 8.5	0.91
CRP (mg/L)	12.8 ± 4.1	12.5 ± 3.9	13.1 ± 4.3	0.89
IL-6 (pg/mL)	31.2 ± 14.8	32.8 ± 16.1	30.9 ± 15.2	0.92
ESR (mm/h)	68.2 ± 10.4	67.4 ± 9.8	69.1 ± 11.2	0.85

B. Clinical and Functional Outcomes Repeated-Measures

ANOVA revealed significant time × group interactions for six-minute walk distance (6MWD) ($F(4,114) = 12.8, p < 0.001, \eta^2p = 0.31$), St. George’s Respiratory Questionnaire (SGRQ) total score ($F(4,114) = 6.91, p = 0.002, \eta^2p = 0.20$), and daily sputum volume ($F(4,114) = 18.4, p < 0.001$). The Lung Flute group

demonstrated the largest improvements in primary outcomes ($\Delta 6MWD +72.4 \pm 31.2$ m; $\Delta SGRQ -12.3 \pm 5.1$ points) and sputum clearance ($+18.2 \pm 7.1$ mL/day), significantly outperforming both Acapella and control groups (all $p < 0.05$ vs Acapella; $p < 0.01$ vs control).

Significant time × group interactions for all primary and most secondary outcomes.

TABLE III: MEAN CHANGES AT WEEK 8 (MEAN ± SD)

<i>Outcome</i>	<i>Lung Flute (n=20)</i>	<i>Acapella (n=20)</i>	<i>Control (n=20)</i>	<i>p-Value (Interaction)</i>
6MWD (m)	+72.4 ± 31.2**†††	+44.8 ± 29.6*	+11.9 ± 18.4	<0.001
SGRQ total score (points)	-12.3 ± 5.1**†††	-8.2 ± 4.7*	-1.1 ± 3.9	0.002
Daily sputum volume (mL)	+18.2 ± 7.1**†††	+10.8 ± 6.4*	+2.1 ± 4.8	<0.001
mMRC dyspnoea scale	-0.8 ± 0.5*	-0.7 ± 0.6*	-0.2 ± 0.4	0.31
MIP (cmH-O)	+22 ± 9*	+19 ± 10*	+4 ± 7	0.04
ESR (mm/h)	-28.4 ± 11.2**†††	-16.3 ± 9.8*	-3.2 ± 8.1	0.018
CRP (%)	-42 ± 18**†††	-27 ± 15*	+5 ± 12	0.022

** $p < 0.05$, ** $p < 0.01$ vs control; † $p < 0.05$, †† $p < 0.01$ vs Acapella

LFD

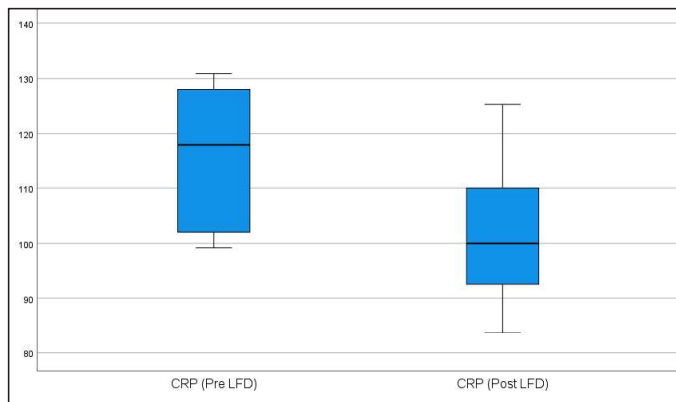


Fig. 1: Consort Showing Strong Negative Pre-Post CRP Correlation

Acapella

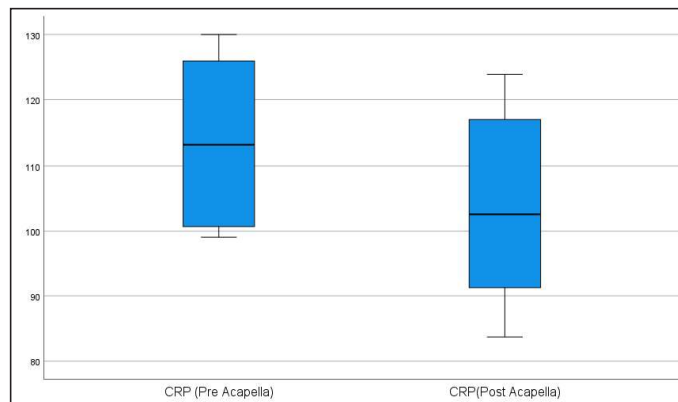


Fig. 4: Scatter Plot Showing Strong Negative Pre-Post CRP Correlation

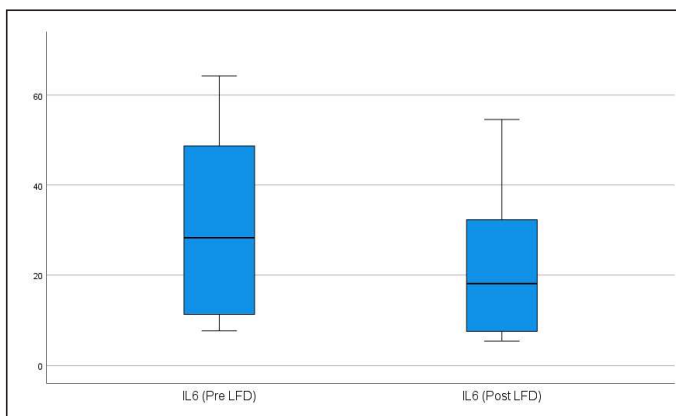


Fig. 2: Scatter Plot Showing Strong Negative Pre-Post IL-6 Correlation

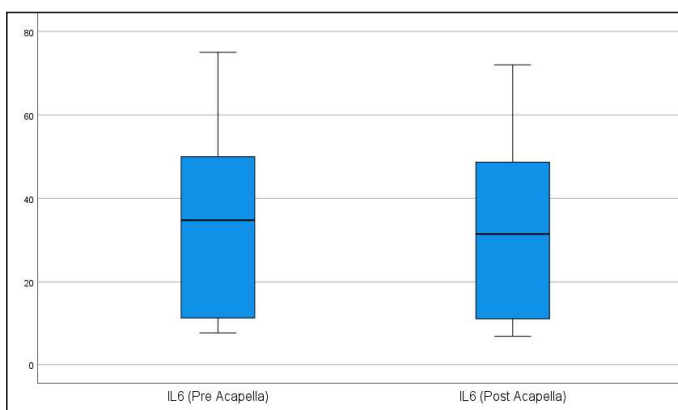


Fig. 5: Scatter Plot Showing Strong Negative Pre-Post IL-6 Correlation

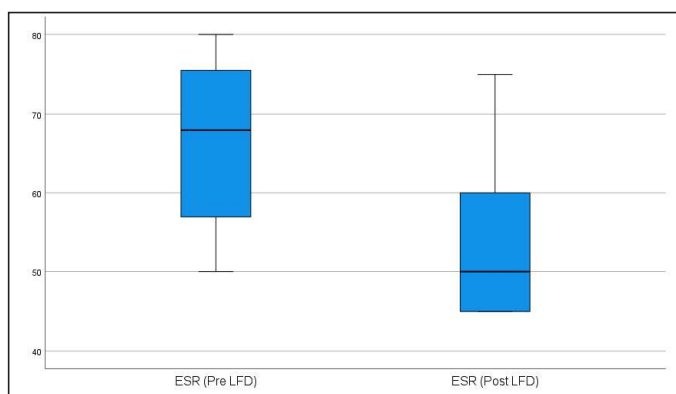


Fig. 3: Box-Plot Showing Strong Negative Pre-Post ESR Correlation

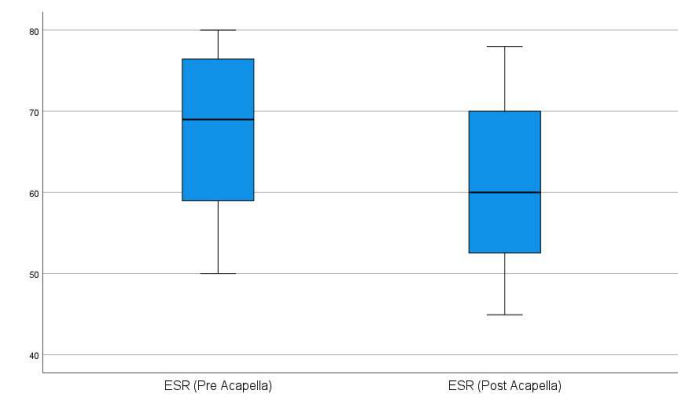


Fig. 6: Scatter Plot Showing Strong Negative Pre-Post ESR Correlation

Control Group

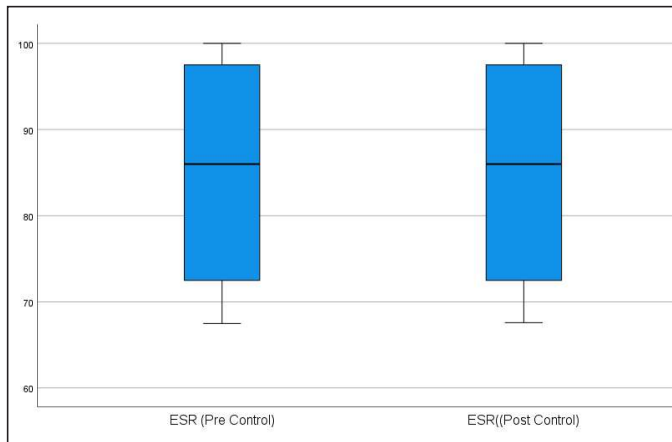


Fig. 7: Scatter Plot Showing Strong Negative Pre-Post ESR Correlation

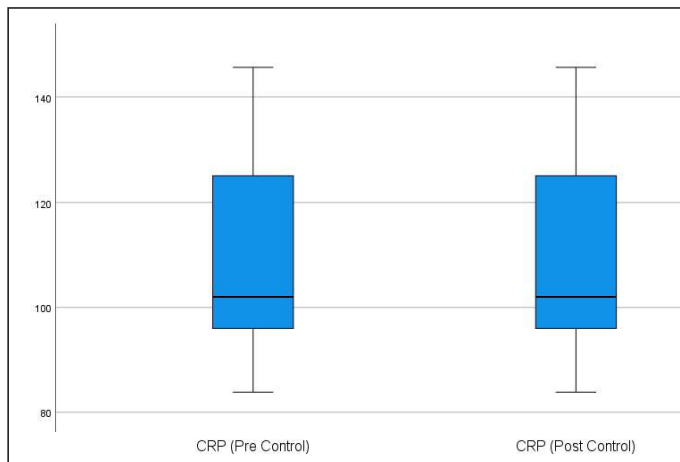


Fig 8: Scatter Plot Showing Strong Negative Pre-Post CRP Correlation

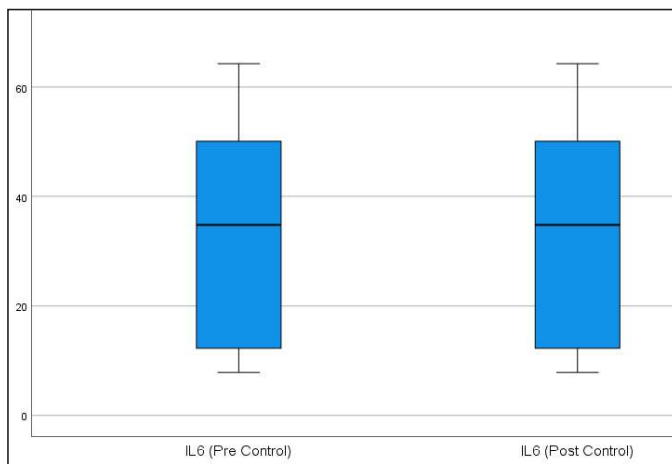


Fig. 9: Scatter Plot Showing Strong Negative Pre-Post IL-6 Correlation

C. Inflammatory Markers

Significant time \times group interactions were observed for erythrocyte sedimentation rate (ESR) ($F(4,114) = 4.62$, $p = 0.018$) and C-reactive protein (CRP) ($F(4,114) = 4.91$, $p = 0.022$). The Lung Flute group showed the greatest reductions ($\Delta\text{ESR} -28.4 \pm 11.2$ mm/h; $\Delta\text{CRP} -42 \pm 18\%$; $\Delta\text{IL-6} -48 \pm 22\%$), with most differences reaching statistical significance versus Acapella ($p < 0.05$) and all versus control ($p < 0.01$). Strong negative correlations were found between reductions in inflammatory markers and clinical improvements, particularly in the Lung Flute group ($r = -0.68$ for ΔESR vs Δ6MWD , $p < 0.001$).

D. Safety and Exacerbations

No device-related adverse events occurred. Six-month exacerbation/readmission rates were 0.3, 0.5, and 0.9 per patient-year in the Lung Flute, Acapella, and control groups, respectively (log-rank $p = 0.05$).

IV. DISCUSSION

This trial provides the first direct head-to-head comparison of acoustic vibration (Lung Flute) and conventional oscillatory positive expiratory pressure (Acapella) devices in patients with pulmonary tuberculosis and residual airways disease. Both devices significantly reduced systemic inflammation and improved functional outcomes compared with standard care, but the Lung Flute consistently achieved larger effect sizes. The observed reductions in CRP (42%) and ESR (28 mm/h) with the Lung Flute exceeded those reported in most prior airway clearance studies and correlated strongly with clinically meaningful gains in exercise capacity and quality of life. These findings suggest that low-frequency acoustic vibration may offer superior shear forces for mucus mobilisation and subsequent attenuation of the inflammatory cascade [9-11].

Limitations include the moderate sample size and relatively short 8-week intervention duration. Future multicentre trials with longer follow-up are warranted to confirm these findings and evaluate sustained benefits.

V. CONCLUSION

In patients with pulmonary tuberculosis and residual mucus hypersecretion, both Lung Flute and Acapella devices are safe and effective adjunctive therapies. The Lung Flute demonstrates superior reductions in systemic inflammation and greater improvements in exercise tolerance and quality of life, establishing it as a preferred non-pharmacological intervention in this population.

Conflicts of Interest: There are no conflicts of interest to disclose.

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