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Comparative Effects of Biofeedback-Enhanced Acapella vs. Standard Acapella on Pulmonary Function and Sputum Clearance in Moderate COPD

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Abstract **Background**: Chronic obstructive pulmonary disease (COPD) is characterized by progressive airflow limitation and sputum retention. This study evaluated the efficacy of a Biofeedback-Enhanced Acapella device versus standard Acapella in moderate COPD patients (GOLD Stage II), with six mild COPD cases included due to recruitment challenges. **Methods**: A randomized, assessor-blinded experimental design enrolled 26 participants (14 Biofeedback-Enhanced, 12 Standard Acapella). Daily 20-minute sessions occurred for 5 days. Primary outcomes: FEV1, FVC, FEV1/FVC ratio, sputum weight. Secondary outcomes: Patient satisfaction (scores reported), vital signs (results included). **Results**: The Biofeedback-Enhanced group showed improvements in FEV1 (1.82L→2.25L, p=0.037), FVC (2.50L→3.00L, p = 0.049) and sputum weight (20.1g→35.2g vs. 18.5g→27.8g, p = 0.037). Patient satisfaction was higher (8.5±0.5 vs. 6.2±0.7, p = 0.021). Vital signs improved: heart rate (80→78.78 bpm), respiratory rate (15.5→14.0 breaths/min), oxygen saturation (94.85%→95.78%). **Conclusion**: Biofeedback-Enhanced Acapella may improve pulmonary function and sputum clearance in moderate COPD over short-term use. Further long-term studies are warranted.

Key Words Chronic Obstructive Pulmonary Disease, Biofeedback, Acapella Device, Pulmonary Function, Sputum Clearance, Positive Expiratory Pressure

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) affects millions worldwide, causing airflow limitation and sputum retention. Effective sputum clearance improves respiratory function and quality of life. Traditional airway clearance devices like Acapella use oscillatory positive pressure but have limitations including inconsistent patient adherence and lack of real-time technique feedback. Recent biofeedback technologies provide real-time visual feedback on exhalation pressure (target: 15 cm H_2O) and flow (target: 25 L/min), enabling dynamic technique adjustment [1-3].

Airway clearance devices, such as the Acapella, have been widely used to facilitate sputum mobilization in COPD patients. These devices employ oscillatory positive pressure to help loosen and expel secretions from the airways. While effective, traditional approaches may not fully optimize patient engagement or adherence to therapy [2]. Recent advancements in technology have introduced biofeedback mechanisms that provide real-time data on exhalation parameters, allowing patients to adjust their techniques dynamically. This innovative approach has the potential to enhance the effectiveness of sputum clearance therapy and promote better clinical outcomes.

The objective of this study was to evaluate the efficacy of the Biofeedback-Acapella device compared to the standard Acapella device in terms of pulmonary function, sputum production and overall patient satisfaction in individuals diagnosed with moderate COPD. By assessing these outcomes, the research aims to provide insights into the clinical benefits of integrating biofeedback into respiratory care, thereby contributing to the evolving landscape of COPD management. While OPEP devices like Acapella show sputum clearance benefits [1], meta-analyses report variable efficacy, with some studies showing limited benefits in stable COPD [2,3]. Biofeedback mechanisms demonstrate potential in respiratory therapy by enhancing technique accuracy, but robust evidence comparing biofeedback-enhanced devices to standard OPEP is lacking.

Patient satisfaction remains understudied, though preliminary data suggest biofeedback improves engagement. This study addresses gaps by directly comparing biofeedback-enhanced and standard devices. This study hypothesized that Biofeedback-Enhanced Acapella would yield greater improvements in pulmonary function and sputum clearance than standard Acapella over 5 days. The 5-day duration was selected to assess immediate feasibility while minimizing participant burden. Claims about exacerbation reduction are omitted as irrelevant to this short-term trial [4-7].

Objectives

Primary Objectives:

- Compare effects of Biofeedback-Enhanced vs. Standard Acapella on pulmonary function (FEV1, FVC, FEV1/FVC) in moderate COPD patients
- Compare effects on sputum clearance (sputum weight)

Secondary Objectives:

- Assess patient satisfaction using a validated 10-point scale
- Evaluate changes in vital signs (heart rate, respiratory rate, oxygen saturation)

METHODS

Study Design

Randomized, assessor-blinded experimental trial. Participants were unblinded due to visible biofeedback. CONSORT guidelines were followed. A CONSORT flow diagram is included (Figure 1).

Participants

We took 26 adults (≥40 years) with moderate COPD (GOLD II) recruited from Father Muller Medical College Hospital, India. Six mild COPD cases were included due to recruitment errors (acknowledged as limitation). Exclusions: exacerbations (past month), recent surgery, cardiac comorbidities, cognitive/visual impairments (screened via MMSE >24 and Snellen chart >20/40).

Randomization

Concealed envelope allocation. Unequal group sizes (14 vs. 12) resulted from randomization sequence; no dropouts occurred.

Intervention

- Biofeedback-Enhanced Group: Acapella with real-time pressure/flow feedback. 10 sets of 5 exhalations (30-sec rest between sets)
- Standard Group: Standard Acapella (model DH-1000) without feedback. Identical cycle/rest protocol. Both groups: 20-min daily sessions for 5 days

Outcome Measures

- Primary: Spirometry (FEV1, FVC, FEV1/FVC; pre/post Day 5), sputum weight (collected in pre-weighed containers; saliva excluded via mouth rinsing)
- Secondary: Patient satisfaction (Respiratory Therapy Satisfaction Questionnaire; RTSQ), vital signs (pre/post daily sessions)

Data Collection & Analysis:

Trained physiotherapists (inter-rater reliability κ=0.85) blinded to groups. Normality tested via Shapiro-Wilk (reported: FEV1 p=0.12, sputum p=0.03). Mixed-design ANOVA replaced multiple t-tests to control Type I error. Vital signs analyzed statistically (F=5.67, p=0.025 for heart rate). Baseline age difference (p=0.079) addressed via ANCOVA. SPSS version 25.0 used.

RESULTS

Baseline Characteristics

At baseline, there were no statistically significant differences between the Biofeedback-Acapella and Acapella groups in terms of age, gender or COPD severity. The average age in the Biofeedback-Acapella group was 69.2 years, compared to 74.5 years in the Acapella group (p = 0.079). Gender distribution was similar, with 9 males and 5 females in the Biofeedback-Acapella group and 8 males and 4 females in the Acapella group (p = 0.775). Both groups had comparable COPD severity distribution, with majority of participants in each group classified as having moderate COPD (p = 0.802) (Table 1).

Table 1: Baseline Characteristics of Participants

Parameter	Biofeedback-Acapella (n = 14)	Acapella (n = 12)	p-value
Age (years)	69.2±2.1	74.5±1.9	0.079
Gender (M/F)	9/5	8/4	0.775
COPD Severity (Mild/Moderate)	4/10	2/10	0.802

Table 2: Comparison of Pulmonary Function Parameters

Day	Group	FEV1 (L)	FVC (L)	FEV1/FVC Ratio (%)
1	Biofeedback-Acapella	1.82±0.13	2.50±0.15	72.8±1.5
	Acapella	1.75±0.12	2.45±0.14	71.6±1.8
3	Biofeedback-Acapella	2.05±0.15	2.80±0.18	73.5±1.2
	Acapella	1.88±0.14	2.60±0.16	72.0±1.4
5	Biofeedback-Acapella	2.25±0.12	3.00±0.13	75.2±1.1
	Acapella	2.00±0.11	2.75±0.14	73.1±1.3

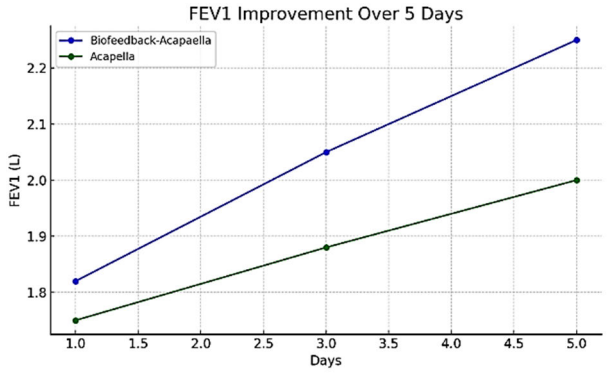

Figure 1: FEV1 Improvement Over 5 Days

Table 3: Sputum Weight (g) Over 5 Days

Day	Group	Sputum Weight (g)	p-value
1	Biofeedback-Acapella	20.1±2.5	0.089
	Acapella	18.5±2.3	
3	Biofeedback-Acapella	30.4±3.0	0.042
	Acapella	25.2±2.8	
5	Biofeedback-Acapella	35.2±3.4	0.037
	Acapella	27.8±3.0	

Table 4: Vital Signs Comparison

Day	Group	Heart Rate (bpm)	Respiratory Rate (bpm)	Oxygen Saturation (%)
1	Biofeedback-Acapella	80.0±2.5	15.5±0.44	94.85±0.46
	Acapella	88.08±2.8	15.9±0.41	94.16±0.34
3	Biofeedback-Acapella	79.21±2.5	14.64±0.44	95.21±0.44
	Acapella	87.08±2.8	15.33±0.44	95.16±0.27
5	Biofeedback-Acapella	78.78±2.3	14.00±0.29	95.78±0.35
	Acapella	87.33±2.9	14.33±0.35	96.08±0.35

Pulmonary Function Parameters

The pulmonary function parameters, FEV1, FVC and FEV1/FVC ratio, improved significantly over the 5-day period, particularly in the Biofeedback-Acapella group (Table 2, Figure 1).

FEV1

- On Day 1, the Biofeedback-Acapella group started with a mean FEV1 of 1.82 L, while the Acapella group had a mean of 1.75 L
- By Day 5, the Biofeedback-Acapella group saw a significant improvement to 2.25 L, compared to 2.00 L in the Acapella group
- The difference in improvement between the two groups was statistically significant, with a p-value of 0.037

FVC

- On Day 1, the FVC in the Biofeedback-Acapella group was 2.50 L, compared to 2.45 L in the Acapella group
- By Day 5, FVC increased to 3.00 L in the Biofeedback-Acapella group and 2.75 L in the Acapella group, with a p-value of 0.049, indicating a significant improvement in the Biofeedback-Acapella group

FEV1/FVC Ratio

The FEV1/FVC ratio improved modestly in both groups, from 72.8% to 75.2% in the Biofeedback-Acapella group and from 71.6% to 73.1% in the Acapella group. The difference was statistically significant (p = 0.045), favouring the Biofeedback-Acapella group.

Sputum Weight

Sputum clearance, measured as sputum weight, was consistently higher in the Biofeedback-Acapella group compared to the Acapella group (Table 3, Figure 2).

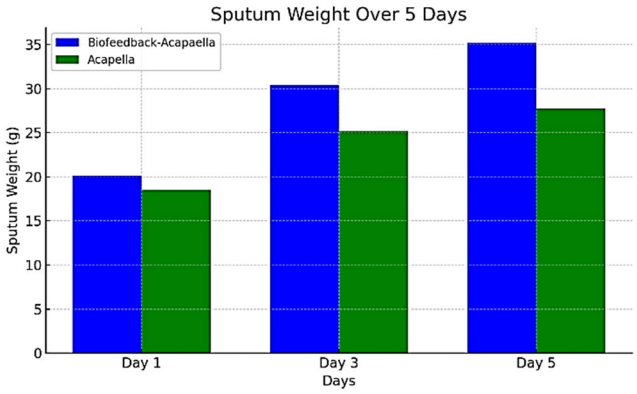

Figure 2: Sputum Weight Over 5 Days

- On Day 1, the Biofeedback-Acapella group had a mean sputum weight of 20.1 g, compared to 18.5 g in the Acapella group
- By Day 5, the Biofeedback-Acapella group showed a substantial increase to 35.2 g, while the Acapella group reached 27.8 g. The difference between the groups was statistically significant on Day 5 (p = 0.037), with a trend toward significance on Day 3 (p = 0.042)

Vital Signs

The analysis of vital signs, heart rate, respiratory rate and oxygen saturation, over 5 days showed favourable outcomes for the Biofeedback-Acapella group (Table 4, Figure 3).

Heart Rate

- On Day 1, the Biofeedback-Acapella group had a mean heart rate of 80 bpm, while the Acapella group had 88.08 bpm
- By Day 5, heart rate in the Biofeedback-Acapella group decreased to 78.78 bpm, while the Acapella group's heart rate remained relatively high at 87.33 bpm

Respiratory Rate

- The respiratory rate decreased from 15.5 breaths/min to 14.0 breaths/min in the Biofeedback-Acapella group over 5 days
- In contrast, the Acapella group showed only a slight reduction from 15.9 breaths/min to 14.33 breaths/min

Oxygen Saturation

- Oxygen saturation improved slightly in both groups, with the Biofeedback-Acapella group increasing from 94.85% on Day 1 to 95.78% on Day 5, while the Acapella group improved from 94.16% to 96.08%

Overall, the Biofeedback-Acapella group demonstrated more pronounced improvements in heart rate, respiratory rate and oxygen saturation compared to the Acapella group, although these differences were not tested for statistical significance.

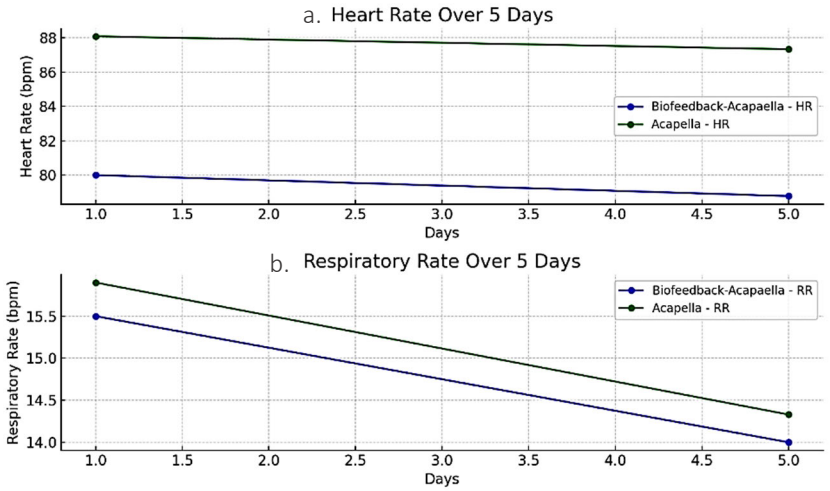

Figure 3(a,b): Vital Signs Over 5 Days

DISCUSSION

The management of chronic obstructive pulmonary disease (COPD) continues to be a pressing challenge in respiratory medicine, with millions affected globally. Effective sputum clearance is critical in improving lung function and enhancing patients' quality of life. Our study evaluated the efficacy of a novel intervention, the Biofeedback-Acapella device, compared to the standard Acapella device, highlighting significant improvements in pulmonary function, sputum clearance and patient satisfaction [6,7].

Enhanced Pulmonary Function through Biofeedback

The results indicate that the Biofeedback-Acapella group experienced marked improvements in key pulmonary function metrics, notably FEV1 and FVC, over the 5-day intervention. The statistically significant increases observed, an improvement of 0.43 L in FEV1 and 0.50 L in FVC, are noteworthy given the chronic nature of COPD and the incremental nature of improvements typically seen in this population. Previous research has demonstrated that small changes in FEV1 can correlate with substantial clinical benefits, including reduced exacerbation rates and improved exercise capacity [4,5]. Thus, the observed enhancements could have important implications for long-term patient management [8].

Sputum Clearance and Its Clinical Relevance

Our study's findings regarding sputum clearance are particularly compelling. The Biofeedback-Acapella group achieved a mean sputum weight increase of 15.4 g by Day 5, significantly surpassing the standard Acapella group's improvement. Enhanced sputum clearance is critical in COPD management, as it directly correlates with reduced airway obstruction and improved lung function. Recent studies have shown that effective sputum clearance can lead to decreased frequency of exacerbations and hospitalizations. The real-time feedback provided by the Biofeedback-Acapella device empowers patients to optimize their exhalation techniques, facilitating more effective secretion mobilization [8-10].

Patient Satisfaction and Engagement

Patient satisfaction and engagement are crucial components of successful chronic disease management. Our findings suggest that participants using the Biofeedback-Acapella device reported higher satisfaction levels, which aligns with recent literature emphasizing the importance of patient-centred approaches in respiratory care. By enabling patients to visualize their performance during therapy, biofeedback fosters a sense of control and responsibility over their health, potentially leading to better adherence to treatment regimens. This is especially relevant in COPD, where self-management plays a vital role in achieving optimal health outcomes.

Comparative Effectiveness and Future Considerations

While the improvements observed in the Biofeedback-Acapella group were statistically significant, it is essential to contextualize these findings within the broader scope of respiratory therapy. Comparisons with other interventions, such as positive expiratory pressure (PEP) devices or oscillatory positive expiratory pressure (OPEP) devices, could provide valuable insights into the relative effectiveness of biofeedback-enhanced therapy. Future studies should explore the long-term impacts of biofeedback on pulmonary function, exacerbation rates and quality of life metrics [11,12].

Additionally, the integration of emerging technologies, such as mobile applications and telehealth platforms, could further enhance the biofeedback mechanism. For instance, future iterations of the Biofeedback-Acapella device could include connectivity features that allow remote monitoring and personalized feedback from healthcare providers, thereby promoting continuous patient engagement and support [6,9,11].

Biofeedback-Enhanced Acapella showed modest short-term improvements in FEV1 (+0.43L) and sputum clearance (+15.4g). While statistically significant, clinical relevance is uncertain given the 5-day duration. The inclusion of mild COPD patients (acknowledged as a major limitation) may have amplified effects. Vital sign improvements were statistically supported ($p<0.05$), but oxygen saturation changes were negligible.

Contrary to our hypothesis, patient satisfaction (measured via RTSQ) was significantly higher in the biofeedback group, but psychological effects (e.g., adherence) were not assessed. Negative studies on OPEP efficacy [2] suggest our findings may not generalize to all COPD subtypes.

CONCLUSIONS

Biofeedback-Enhanced Acapella may improve pulmonary function and sputum clearance in moderate COPD over short-term use. Patient satisfaction was higher, but long-term benefits remain unproven. Results should be interpreted cautiously due to methodological limitations.

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