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Chest physiotherapy for pulmonary function in head and neck malignancy: A randomized controlled trial

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Abstract:
Composite resection for head and neck malignancy carries a high risk of post-operative pulmonary complications. This randomized controlled trial included 60 adults assigned to structured chest physiotherapy or standard care. At post-operative day 7, physiotherapy significantly improved FVC, FEV1, chest expansion and oxygen saturation ($p<0.001$). Pulmonary complications were lower with physiotherapy (10.0% vs. 30.0%; $p=0.049$), with shorter ICU and hospital stays. Thus, structured chest physiotherapy improved pulmonary recovery and reduced complications after composite resection.

Keywords: Chest physiotherapy, composite resection, commando procedure, head and neck cancer, pulmonary function, post-operative pulmonary complications, randomized controlled trial (RCT), pulmonary rehabilitation

Background:
Head and neck squamous cell carcinoma remains a major malignancy in South Asia, largely associated with tobacco and areca-nut use **[1]**. Composite resection involves mandibulectomy, neck dissection and en-bloc primary tumour resection, often followed by flap reconstruction **[2]**. The extensive surgery, prolonged anaesthesia, tracheostomy, post-operative pain and impaired cough can reduce lung volumes, impair secretion clearance and increase the risk of atelectasis and pneumonia **[3]**. Post-operative pulmonary complication rates after major head and neck cancer surgery range from approximately 15-45% and are associated with prolonged ICU and hospital stays **[4]**. Structured chest physiotherapy, including breathing exercises, incentive spirometry, airway-clearance techniques and early mobilization, has been shown to reduce pulmonary complications after major surgery **[5]**. In head and neck cancer, observational evidence also suggests benefits from structured respiratory rehabilitation **[6]**. However, randomized evidence specifically evaluating physiotherapist-led chest physiotherapy after composite resection remains limited **[7, 8].** Therefore, it is of interest to evaluate the effect of structured chest physiotherapy on pulmonary function and post-operative pulmonary outcomes following composite resection for head and neck malignancy.

Materials and Methods:

Trial design:
This was a prospective, assessor-blinded, parallel-group, two-arm randomized controlled trial conducted in accordance with the Declaration of Helsinki and reported in line with the CONSORT 2010 recommendations **[10]**. Written informed consent was obtained from all participants prior to enrolment.

Setting:
Patients were recruited from the Department of Otorhinolaryngology-Head and Neck Surgery / Surgical Oncology of a tertiary care teaching hospital, with the physiotherapy intervention delivered by the Department of Physiotherapy.

Participants:
Adults of either sex scheduled for elective composite resection (segmental/marginal mandibulectomy with ipsilateral neck dissection and primary tumour excision, with or without pedicled or free-flap reconstruction) for histologically confirmed oral or oropharyngeal squamous cell carcinoma were screened for eligibility.

Inclusion criteria:
[1] Age 18-70 years.
[2] Scheduled for elective composite resection (commando procedure) for head and neck malignancy.
[3] American Society of Anesthesiologists (ASA) physical status I-III.

[4] Preoperative FVC and FEV1 ≥ 70% of predicted.
[5] Able to follow verbal/written instructions and cooperate with spirometric testing.

Exclusion criteria:
[1] Pre-existing severe chronic respiratory disease (*e.g.,* severe COPD, interstitial lung disease) or unstable cardiac disease.
[2] Distant metastatic disease or planned palliative surgery.
[3] Preoperative pneumonia or active respiratory infection.
[4] Neuromuscular or musculoskeletal conditions precluding participation in exercise-based physiotherapy.
[5] Reoperation/revision surgery or emergency procedures.
[6] Refusal of consent.

Sample size:
Sample size was estimated using G*Power version 3.1 **[11]** for a two-tailed independent-samples t-test on the primary outcome (change in FVC from baseline to POD7), assuming a large effect size (Cohen's d = 0.80) based on comparable post-operative chest-physiotherapy literature, α = 0.05 and power (1−β) = 0.80. This yielded a minimum requirement of 26 participants per group. Allowing for an expected 15% attrition (loss to follow-up, incomplete spirometry, early discharge against medical advice), a target of 30 participants per group (N = 60) was adopted.

Randomization and allocation concealment:
Eligible, consenting participants were randomized 1:1 to the structured chest physiotherapy group or the standard care group using a computer-generated random-number sequence with block randomization (block size 4-6), stratified by planned reconstruction type (pedicled flap vs free flap). Allocation was concealed using sequentially numbered, opaque, sealed envelopes opened only after baseline (preoperative) assessment by an investigator not involved in outcome assessment. Because the intervention was physiotherapy, physiotherapists and patients could not be blinded to group allocation; however, the outcome assessor recording spirometric and clinical data was blinded to group allocation throughout the study (assessor-blinded design).

Interventions:
Structured chest physiotherapy group (intervention):
In addition to routine post-operative medical and nursing care, participants received a predetermined, physiotherapist-supervised chest physiotherapy programme, starting on POD1 (when medically stable) and continued twice daily (morning and evening) until hospital discharge. Each session (about 20-30 minutes) included:
[1] Diaphragmatic and segmental breathing exercises (5-10 repetitions per set)
[2] Incentive spirometry (10 sustained maximal inspirations per session, with target-volume feedback)
[3] Thoracic expansion exercises with end-inspiratory hold and manual/verbal facilitation as tolerated
[4] Directed, effective coughing and huffing techniques with manual wound/flap-protective support
[5] Early progressive mobilization: assisted sitting on POD1, standing/marching on POD 1-2 and progressive ambulation thereafter as surgically allowed
[6] Positioning recommendations and, where necessary, gentle manual/postural airway clearance of retained secretions

Standard care group (control): Participants received routine post-operative nursing and medical care, including as-needed tracheal/oral suctioning, encouragement of early mobilization at the surgical team's discretion and analgesia, but did not receive a structured, protocolized physiotherapy programme or supervised breathing/incentive-spirometry sessions unless clinically indicated for an evolving complication (in which case the participant's data were analysed by intention-to-treat).

Outcome measures:
Primary outcome:
Change in FVC and FEV1 (measured by portable spirometry, best of three technically acceptable efforts, ATS/ERS criteria) from baseline (preoperative) to POD7.

Secondary outcomes:
PEFR; FEV1/FVC ratio; chest expansion (axillary and xiphoid level, cm, measured by inelastic tape); resting SpO2 (pulse oximetry); incidence of PPCs (atelectasis, pneumonia, defined by standard radiological and clinical criteria); ICU length of stay; total hospital length of stay; and time to first out-of-bed ambulation. Assessments were performed at three time points: baseline (within 24 hours preoperatively), POD7 and POD14 or discharge, whichever occurred first.

Statistical analysis:
Data were analysed using SPSS (version 26.0 or later). Normality was assessed using the Shapiro-Wilk test. Between-group comparisons of normally distributed continuous variables used the independent-samples t-test; non-normally distributed variables used the Mann-Whitney U test. Within-group change over time was assessed using repeated-measures ANOVA (or the Friedman test for non-normal data) with post-hoc pairwise comparisons. Categorical variables (*e.g.,* PPC incidence, sex distribution) were compared using the chi-square test or Fisher's exact test where expected cell counts were <5. A two-tailed p-value <0.05 was considered statistically significant. Analysis followed the intention-to-treat principle.

Results:
Sixty-eight patients were assessed for eligibility; 60 met the inclusion criteria, consented and were randomized (30 to structured chest physiotherapy, 30 to standard care). One participant in the standard-care group was lost to follow-up after POD7 (early discharge against medical advice) and was included in the intention-to-treat analysis using last-observation-carried-forward for the POD14 endpoint. No participant in the intervention group was lost to follow-up. Baseline demographic and clinical characteristics were comparable between groups **(Table 1),** with no statistically significant between-group

differences (all p>0.05), indicating adequate randomization. Both groups showed a decline in FVC and FEV1 by POD7 relative to baseline, reflecting the expected post-operative restrictive pattern; however, the decline was significantly smaller in the structured chest physiotherapy group. At POD7, FVC was 2.09 ± 0.35 L in the intervention group versus 1.72 ± 0.33 L in the standard-care group (mean difference 0.37 L, 95% CI 0.20-0.54, p<0.001) and FEV1 was 1.68 ± 0.29 L versus 1.31 ± 0.27 L, respectively (p<0.001). By POD14/discharge, the intervention group had recovered to approximately 87.8% of baseline FVC compared with 74.0% in the standard-care group (**Table 2**). Chest expansion and resting oxygen saturation at POD7 were significantly greater in the structured chest physiotherapy group. The incidence of PPCs was lower in the intervention group (3/30, 10.0%: 2 atelectasis, 1 pneumonia) than in the standard-care group (9/30, 30.0%: 6 atelectasis, 3 pneumonia; χ^2 = 4.32, p=0.049). ICU stay (2.1 ± 0.7 vs 2.9 ± 1.1 days, p=0.002), total hospital stay (10.4 ± 2.1 vs 13.6 ± 2.8 days, p<0.001) and time to first ambulation (18.6 ± 4.2 vs 27.3 ± 5.6 hours, p<0.001) were all significantly lower/shorter in the structured chest physiotherapy group **(Table 3).**

Table 1: Baseline demographic and clinical characteristics (mean ± SD or n [%])

Variable	Structured CPT (n=30)	Standard care (n=30)	p-value
Age (years)	54.2 ± 8.6	55.8 ± 9.1	0.487
Sex, male / female	24 (80.0%) / 6 (20.0%)	23 (76.7%) / 7 (23.3%)	0.762
BMI (kg/m²)	23.6 ± 3.1	23.9 ± 3.4	0.712
ASA grade I / II / III	9/17/2004	8/18/2004	0.941
Smoking history, n (%)	18 (60.0%)	17 (56.7%)	0.793
Tumour site (buccal mucosa / tongue / GB sulcus / other)	12 / 9 / 6 / 3	11 / 10 / 5 / 4	0.902
Reconstruction: pedicled flap / free flap	19 / 11	18 / 12	0.795
Baseline FVC (L)	2.86 ± 0.42	2.81 ± 0.39	0.641
Baseline FEV1 (L)	2.31 ± 0.38	2.27 ± 0.35	0.687
Baseline FEV1/FVC (%)	80.8 ± 5.2	80.4 ± 5.6	0.774
Baseline PEFR (L/min)	6.42 ± 1.05	6.35 ± 1.12	0.803

CPT, chest physiotherapy; ASA, American Society of Anesthesiologists; BMI, body mass index; FVC, forced vital capacity; FEV1, forced expiratory volume in one second; PEFR, peak expiratory flow rate; GB, gingivobuccal.

Table 2: Pulmonary function at baseline, POD7 and POD14/discharge

Parameter / time point	Structured CPT (n=30)	Standard care (n=30)	p-value (between-group)
FVC (L) - baseline	2.86 ± 0.42	2.81 ± 0.39	0.641
FVC (L) - POD7	2.09 ± 0.35	1.72 ± 0.33	<0.001
FVC (L) - POD14/discharge	2.51 ± 0.38	2.08 ± 0.36	<0.001
FEV1 (L) - baseline	2.31 ± 0.38	2.27 ± 0.35	0.687
FEV1 (L) - POD7	1.68 ± 0.29	1.31 ± 0.27	<0.001
FEV1 (L) - POD14/discharge	2.02 ± 0.31	1.62 ± 0.30	<0.001
FEV1/FVC (%) - POD7	79.9 ± 5.0	76.6 ± 5.8	0.021
PEFR (L/min) - POD7	4.35 ± 0.88	3.42 ± 0.79	<0.001
PEFR (L/min) - POD14/discharge	5.61 ± 0.95	4.48 ± 0.87	<0.001

CPT, chest physiotherapy; FVC, forced vital capacity; FEV1, forced expiratory volume in one second; PEFR, peak expiratory flow rate; POD, post-operative day.

Table 3: Secondary clinical outcomes

Parameter / time point	Structured CPT (n=30)	Standard care (n=30)	p-value (between-group)
FVC (L) - baseline	2.86 ± 0.42	2.81 ± 0.39	0.641
FVC (L) - POD7	2.09 ± 0.35	1.72 ± 0.33	<0.001
FVC (L) - POD14/discharge	2.51 ± 0.38	2.08 ± 0.36	<0.001
FEV1 (L) - baseline	2.31 ± 0.38	2.27 ± 0.35	0.687
FEV1 (L) - POD7	1.68 ± 0.29	1.31 ± 0.27	<0.001
FEV1 (L) - POD14/discharge	2.02 ± 0.31	1.62 ± 0.30	<0.001
FEV1/FVC (%) - POD7	79.9 ± 5.0	76.6 ± 5.8	0.021
PEFR (L/min) - POD7	4.35 ± 0.88	3.42 ± 0.79	<0.001
PEFR (L/min) - POD14/discharge	5.61 ± 0.95	4.48 ± 0.87	<0.001

CPT, chest physiotherapy; ICU, intensive care unit; SpO2, peripheral oxygen saturation; POD, post-operative day.
No adverse events attributable to the chest physiotherapy protocol (e.g., flap compromise, wound dehiscence) were recorded in either group.

Discussion:

In this randomized controlled trial, a structured, physiotherapist-directed chest physiotherapy protocol produced significantly better preservation and recovery of pulmonary function, fewer PPCs and shorter ICU and hospital stay than standard care in patients undergoing composite resection for head and neck malignancy. These findings extend the existing evidence base - largely derived from observational cohorts and retrospective series in head and neck oncologic surgery - into a prospective, randomized, assessor-blinded framework focused specifically on the composite-resection (commando) subgroup. The magnitude of post-operative pulmonary function decline observed in the standard-care arm is consistent with previously reported high rates of PPCs after major head and neck cancer surgery with free-flap reconstruction, where PPC incidence has been reported in the range of 15-45% depending on diagnostic criteria and case mix **[9].** Composite resection combines several independent risk factors for PPCs identified in earlier work - prolonged operative time, tracheostomy, extensive neck dissection and reduced early mobility - which may explain why

the pulmonary function decline and complication burden observed here in the standard-care arm were at the higher end of previously reported ranges **[10].** Mechanistically, the benefit of structured chest physiotherapy in this population plausibly reflects several converging effects: diaphragmatic and thoracic expansion exercises and incentive spirometry counteract the restrictive ventilatory pattern induced by prolonged supine positioning, pain-limited chest-wall movement and tracheostomy; directed coughing/huffing with wound-protective support improves secretion clearance despite impaired volitional cough strength; and early progressive mobilization reduces the duration of dependent atelectasis. These mechanisms parallel those proposed for the well-established benefit of respiratory physiotherapy after upper abdominal and cardiothoracic surgery **[6-8]**. Perioperative respiratory-optimization strategies - including physiotherapy, along with adjuncts such as pre-emptive ventilatory support or point-of-care lung-ultrasound-guided atelectasis bundles - have similarly shown benefit specifically in cervicofacial and head and neck oncologic surgery populations **[11].** The reduction in ICU and total hospital stay observed with structured chest physiotherapy has direct resource and cost implications for high-volume head and neck oncology centres, particularly in resource-constrained settings where ICU bed availability is limited. Given that PPCs are independently associated with prolonged mechanical ventilation and increased cost of care, even a modest absolute risk reduction of the magnitude observed here (20 percentage points) may translate into meaningful system-level benefit if confirmed in larger, multicentric trials **[12]**. Clinically, these results support routine integration of a structured, protocolized chest physiotherapy pathway - rather than ad hoc or as-needed physiotherapy referral - into standard perioperative care for patients undergoing composite resection, ideally initiated as early as POD1 once the patient is haemodynamically and surgically stable and continued at least twice daily until discharge **[13]**.

Conclusion:

Structured chest physiotherapy significantly improved post-operative pulmonary function and reduced PPCs in patients undergoing composite resection for head and neck malignancy. Early physiotherapy also shortened ICU and hospital stays compared with standard care. Routine integration into perioperative care is recommended, pending confirmation through larger multicentre randomized trials.

Limitations:

Single-centre design with a moderate sample size may limit generalizability; multicentric confirmation is warranted. Blinding of participants and treating physiotherapists to group allocation was not feasible given the nature of the intervention, although the outcome assessor remained blinded. Long-term (>14 days) pulmonary and functional outcomes and quality-of-life measures, were not assessed and warrant future study. PPC classification relied on standard clinical/radiological criteria rather than a single validated composite scoring tool (*e.g.,* the Melbourne Group Scale), which may affect comparability with some prior studies.

Conflict of interest: The authors declare no conflict of interest.

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