

A Phase II Randomized Control Study to Assess The Efficacy of Curcumin and Honey in Cough on Patients with Lung Cancer at A Tertiary Cancer Center, Hbni, Mumbai

Prathepa Jagdiish^{1*}, Snehal Shinde¹, Vijay Patil², Vanita Noronha², Nandini Menon², KumarPrabash², Vikram Ghoti³ and Akash Pawar⁴

¹Professor and PG student College of Nursing ,
TMH, HBNI ,Parel, Mumbai, India

²Professors, Department of Medical Oncology
,Parel, HBNI, Mumbai, India

³Department of Pharmacy,ACTREC, TMH, HBNI,
India

⁴Department of statistics TMH, HBNI, India

*Corresponding Author

Prathepa Jagdiish. Professor and PG student College of Nursing, TMH, HBNI, Parel, Mumbai, India.

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Abstract

Introduction: Lung cancer is the most important cancer in men and the 2nd most common cancer in women in India with the largest fatality. Squamous cell carcinoma and small cell undifferentiated lung cancer are more likely to be associated with cough. Symptoms include dyspnea, persistent cough and haemoptysis. In these scenarios curcumin represents a promising and effective anticancer drug to be used alone or in combination with other drugs to treat cough. It affects different signalling pathways and molecular targets involved in the development of several cancers. Its biological activities such as antioxidant, anti-inflammatory, antimicrobial, antiviral, among which its anticancer potential has been the most described. Honey is rich in flavonoids. Flavonoids have their anticancer properties. The mechanisms suggested are rather diverse such as various signalling pathways, including stimulation of TNF- α release, inhibition of cell proliferation, induction of apoptosis and cell cycle arrest as well as inhibition of lipoprotein oxidation.

Objectives: Primary objective was to assess the efficacy of curcumin and honey on cough in patients with lung cancer at a tertiary cancer centre. Secondary objectives were to assess incidence & degree of cough, to find out the association between clinical data and efficacy of curcumin and honey.

Methodology: Quantitative approach with randomized controlled trial (open labelled) design. Targeted Population Lung cancer patients with cough. Total 52 patients participated in the study. Control arm participants received standardized treatment with no intervention. Participants from experimental arm had curcumin 500mg with 5 ml of honey mixed together for three times a day orally for 21 days. Cough visual analogue scale was used. Data were analysed using descriptive and inferential statistics using SPSS version 25.

Results: Mann Whitney U test was carried to check difference between control and intervention group on day 0, day 10 and day 22. It was found that for CVAS p value was < 0.05 , indicating a statistically significant difference in the experimental arm.

1. Introduction

Lung cancer is the most common cancer in men and the 2nd most common cancer in women with a larger fatality [1-2]. with more than 2.2 million new cases of lung cancer in 2020 [3]. Most lung cancer statistics include both small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC) [4-10]. There can be tumours from other diseases like lymphoma or tuberculosis [11-14]. Most lung cancer can be associated with cough. Squamous cell carcinoma and small cell undifferentiated lung cancer are more likely to be associated with cough It includes chronic cough usually lasting more than 8 consecutive weeks, a cough that is either dry or productive and interferes with sleep and haemoptysis [15-16]. Cough occurs by the irritation of cough receptors. Chemical receptors sensitive capsaicin-like compounds trigger the cough reflex via activation of the type 1 vanilloid capsaicin receptor. Impulses from stimulated cough receptors traverse an afferent pathway via the vagus nerve to a cough centre in the medulla [17-22]. Many studies suggest that curcumin exhibits a broad range of anti-cancerous properties like antioxidants, anti-inflammatory, antiproliferative and anti-immunomodulatory effects. Manuka, pasture and jelly bush honey were found to significantly increase TNF- α , IL-1 β , and IL-6 release from MM6 cells and human monocytes when compared with untreated and artificial honey-treated cells [23]. On the basis of Lung Cancer Symptoms Scale, Iyer et al proved that the most frequent symptoms include fatigue (98%), loss of appetite (98%), respiratory problems(94%), cough (93%), pain (90%) and blood in sputum (70%). Additionally, correlation analysis showed that the greater the severity of symptoms, the lower the QOL [24-25]. Suppression of cough is not always the aim of treating cough among patients with lung cancer [26]. Many of the patients with lung cancer report a dry tickling cough and current antitussive treatments are suboptimal. Potassium iodide, bromhexine and amroxol used as mucolytic for wet cough leads to increased broncho secretion, lessens viscosity, hypothyroidism, blurred vision, drowsiness or dizziness., nausea or vomiting Curcumin has anticarcinogenic, anti-tumour, antiviral, antibacterial, antifungal and antiplatelet activity [27]. It inhibits multiple signalling

pathways such as nuclear factor kappaB cyclooxygenase-2 and interleukin-8. Curcumin has anticancer potential through the modulation of multiple cell signalling pathways. Honey has potent mechanism of anti-cancer activity. The possible mechanisms are due to its apoptotic, antiproliferative, antitumor necrosis factor, antioxidant, anti-inflammatory, estrogenic and immunomodulatory activities. Investigator seeks to understand the efficacy of honey and curcumin as a natural supplement for cough in lung cancer patients.

Primary objective was to assess the efficacy of curcumin and honey on cough in patients with lung cancer at a tertiary cancer centre. Secondary Objectives were to assess incidence & degree of cough and to define the association between clinical data and efficacy of curcumin and honey. Materials and methods - quantitative research approach This was an open labelled, prospective, randomized controlled study using sealed envelope technique. Institutional Ethics Committee approval number was 4109 and CTRI approval(CTRI/2023/6/54088). The samples were selected based on inclusion and exclusion criteria with sample size of 52 and informed consent Inclusion Criteria -Patients diagnosed of proven lung cancer with cough, Cough severity with ≥ 40 mm as per cough VAS, patients who were on NACT /Adjuvant, Age group 18-65years, ECOG score 0-2, Willing to participate in study and followed Marathi/Hindi or English and exclusion criteria was patients with lung metastasis and with diabetes mellitus. Data collection was done using CVAS tool. Evaluation of tool - Mild 0-33mm, Moderate - 34mm-67mm, Severe was 68mm-100mm. Method – Post randomization, allocation was done. Baseline assessment was obtained on day 0 for both groups. Intervention provided to experimental arm with curcumin 500mg and 5 ml of honey a mix made by patient for three time a day. Orally consumed for 21 days. Control arm had no intervention. Second time point assessments were day 10 and day 22 for both groups.

2. Results

Variables	Categories	Control Arm A	%	Experimental Arm B	%
Sex	Female	10	58.8%	7	41.2%
	Male	16	45.7%	19	54.3%
income_cat	<10,000	6	60.0%	4	40.0%
	10,000-20,000	12	41.4%	17	58.6%
	21,000-30,000	6	66.7%	3	33.3%
	31,000-40,000	2	50.0%	2	50.0%
Diagnosis_cat	Lung carcinoid	2	66.7%	1	33.3%
	Squamous cell carcinoma of lung	7	38.9%	11	61.1%
	Adenocarcinoma carcinoma	14	56.0%	11	44.0%
	Epithelioid Hemangioendothelioma EHE	1	50.0%	1	50.0%

	Spindle cell carcinoma in lung	0	0.0%	1	100.0%
	Undifferentiate round cell sarcoma of lung	1	100.0%	0	0.0%
	small cell lung cancer	1	100.0%	0	0.0%
	synovial sarcoma	0	0.0%	1	100.0%
Treatment	Adjuvant	9	50.0%	9	50.0%
	NACT	4	50.0%	4	50.0%
	Under diagnostic evaluation	13	50.0%	13	50.0%
ECOG	0	3	75.0%	1	25.0%
	1	19	43.2%	25	56.8%
	2	4	100%	0	0.0%
T_stage	T1	2	50.0%	2	50.0%
	T2	8	72.7%	3	27.3%
	T3	12	60.0%	8	40.0%
	T4	4	23.5%	13	76.5%
N_stage	No	7	46.7%	8	53.3%
	N1	5	83.3%	1	16.7%
	N2	7	38.9%	11	61.1%
	N3	3	50.0%	3	50.0%
	N2/3	4	57.1%	3	42.9%
M_stage	Mo	21	55.3%	17	44.7%
	M1	5	35.7%	9	64.3%
Tobacco	Yes	4	50.0%	4	50.0%
	No	22	50.0%	22	50.0%
Smoking	Yes	13	50.0%	13	50.0%
	No	13	50.0%	13	50.0%
Pan masala	Yes	1	33.3%	2	66.7%
	No	25	51.0%	24	49.0%
Alcohol	Yes	4	57.1%	3	42.9%
	No	22	48.9%	23	51.1%
Hypertension	Yes	7	53.8%	6	46.2%
	No	19	48.7%	20	51.3%
Tuberculosis	Yes	4	50.0%	4	50.0%
	No	22	50.0%	22	50.0%
Covid	yes	0	0.0%	2	100.0%
	No	26	52.0%	24	48.0%
Oher diseases	Yes	5	55.6%	4	44.4%
	No	21	48.8%	22	51.2%
Grade 1	Moderate	24	60.0%	16	40.0%
	Severe	2	16.7%	10	83.3%
Grade 2	Mild	9	52.9%	8	47.1%
	Moderate	16	53.3%	14	46.7%
	Severe	1		4	
Grade 3	Moderate	13	76.5%	4	23.5%
	No cough	2	66.7%	1	33.3%
	Severe	2	66.7%	1	33.3%
Occupation	Farmer	3	37.5%	5	62.5%

	Homemaker	8	61.5%	5	38.5%
	labour	4	36.4%	7	63.6%
	Service	3	42.9%	4	57.1%
	unemployed	5	62.5%	3	37.5%
	other	3	60.0%	2	40.0%
Family history	Yes	7	63.6%	4	36.4%
	No	19	46.3%	22	53.7%
Total		26	50.0%	26	50.0%

Table 1: Distribution of Demographic and Clinical variables in control and Experimental arm . n=52

Section II

	Mean	N	Std. Deviation	Mean Difference	Std Deviation	P
CVASscore1	49.2308	26	11.87542	11.53846	21.15268	0.073
CVASscore2	37.6923	26	19.64427			
CVASscore2	37.6923	26	19.64427	6.15385	16.09268	0.193
CVASscore3	31.5385	26	25.44476			
CVASscore1	49.2308	26	11.87542	17.69231	27.73501	0.040
CVASscore3	31.5385	26	25.44476			

Table 2: Compares the CVAS scores between day1, day 10 and day 22 in Control Arm A

	Mean	N	Std. Deviation	Mean Difference	Std Deviation	P
CVASscore1	60.0000	26	19.57890	16.53846	9.87096	0.000
CVASscore2	43.4615	26	22.11566			
CVASscore2	43.4615	26	22.11566	13.84615	9.38835	0.000
CVASscore3	29.6154	26	21.45359			
CVASscore1	60.0000	26	19.57890	30.38462	12.98421	0.000
CVASscore3	29.6154	26	21.45359			

Table 3. Represents Compares the CVAS scores of day1, day 10 and day 22 in Experimental Arm B

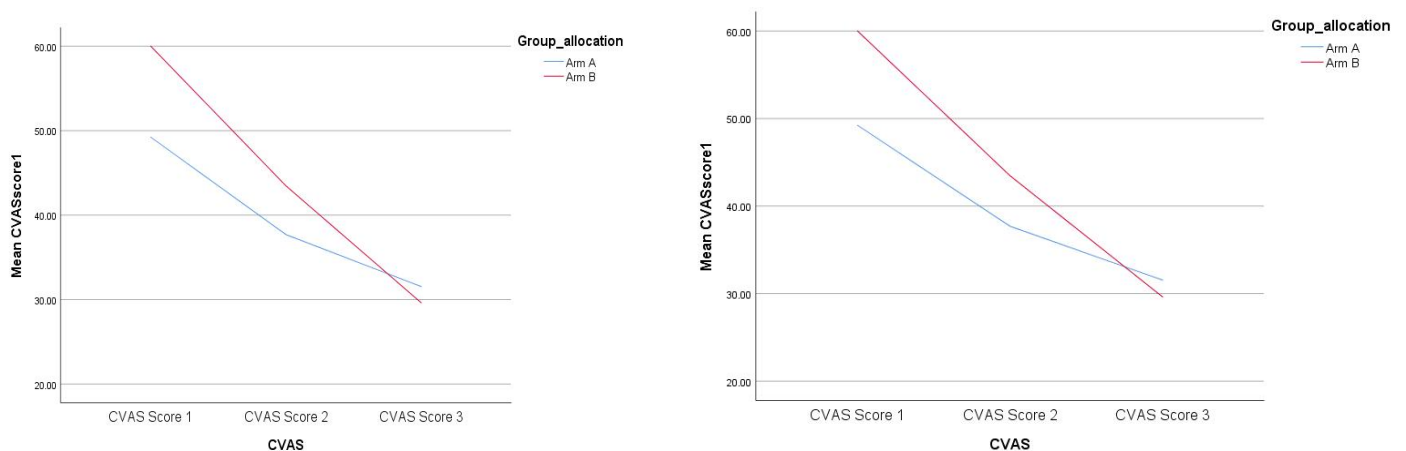


Figure 2: Graph Represent mean of CVAS between Control Arm A and Experimental Arm B

There are statistically significant differences between CVAScore1 and CVAScore2, between CVAScore2 and CVAScore3, and between CVAScore1 and CVAScore3, as all the corresponding P-values were less than 0.05..

DAY 1		Control Arm A	%	Experimental Arm B	%		Control Arm A	%	Experimental Arm B	%	TOTAL	%	
CVAS SCORE day 1	Severe	2	7.7%	10	38.5%	CVAS SCORE day 22	Severe	2	7.7%	2	7.7%	4	7.7%
	Moderate	24	92.3%	16	61.5%		Moderate	10	38.5%	4	38.5%	14	38.5%
	Mild	0		0			Mild	14	53.8%	20	53.8%	34	53.8%
	total	26	100%	26	100%			26	100%	26	100%	52	100%

Table 4: Represent the Efficacy of Experimental Arm B over Control Arm A for Degree of Cough Pre-Treatment between day 1 and day 22

	Control arm A	%	Control Arm B	%	TOTAL	%	
CVAS SCORE 3	Severe	2	7.7%	2	7.7%	4	7.7%
	Moderate	10.7	38.5%	4	38.5%	14	38.5%
	Mild	14	53.8%				
	20	53.8%	34	53.8%			
	Total	26	100%	26	100%	52	100%

Table 5: Represents the Degree of Cough in both Arms on day 22

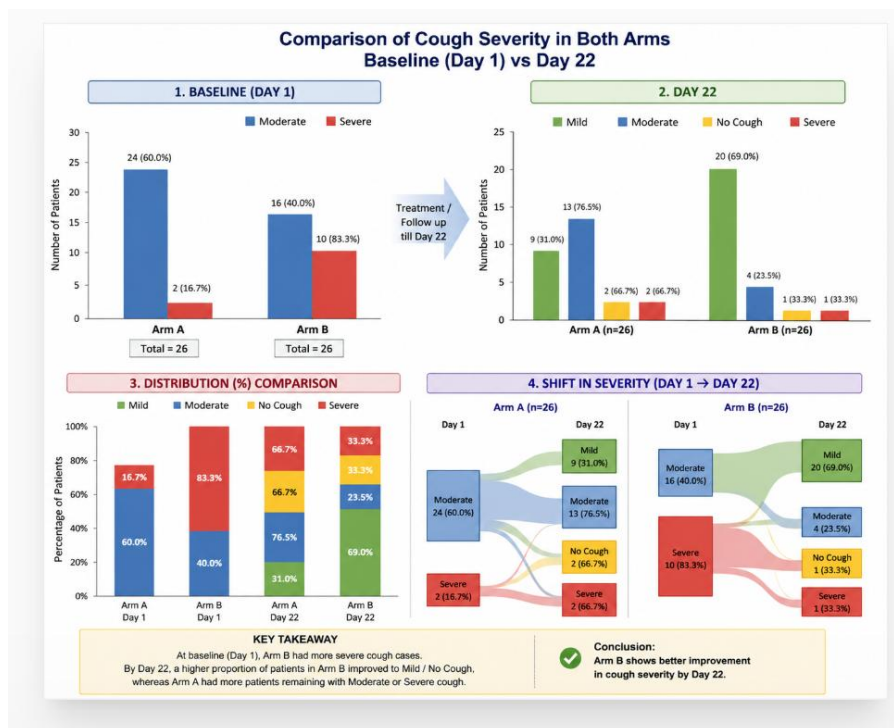


Figure 2: Graph Representing the Change of Shift of Severity of Cough in Experimental and Control Arms

Section-III

Variables	Categories	Total	P value
Sex	Female	17	0.375
	Male	35	
Income	<10,000	10	0.52
	10,000-20,000	29	
	21,000-30,000	9	
	31,000-40,000	4	
Diagnosis_cat	Lung carcinoid	3	0.589
	Squamous cell carcinoma of lung	18	
	Adenocarcinoma carcinoma	25	
	Epithelioid Hemangioendothelioma EHE	2	
	Spindle cell carcinoma in lung	1	
	Undifferentiate round cell sarcoma of lung	1	
	small cell lung cancer	1	
	synovial sarcoma	1	
	Treatment_cat	Adjuvant	
	NACT	8	
	Unser diagnostic evaluation	26	
ECOG	0	4	0.055
	1	44	
	2	4	
T_stage	T1	4	0.049
	T2	11	
	T3	20	
	T4	17	
N_stage_cat	No	15	0.439
	N1	6	
	N2	18	
	N3	6	
	N2/3	7	
M_stage_cat	Mo	38	0.211
	M1	14	
Tobacco	Yes	8	1
	No	44	
Smoking	Yes	26	1
	No	26	
Panmasala	Yes	3	0.522
	No	49	
	No	45	
Hypertension	Yes	13	0.749
	No	39	
Tuberculosis	Yes	8	1

	No	44	
Covid	yes	2	0.149
	No	50	
Other diseases_	Yes	9	0.714
	No	43	
Grade 1	Moderate	40	0.008
	Severe	12	
Grade 2	Mild	17	0.369
	Moderate	30	
	Severe	5	
Grade 3	Mild	29	0.022
	Moderate	17	
	No cough	3	
	Severe	3	
Occupation	Farmer	8	0.723
	Homemaker	13	
	labour	11	
	Service	7	
	unemployed	8	
	other	5	
Family history	Yes	11	0.308
	No	41	
Total		52	

Table 6: Associations Of demographic, clinical data with CVAS Score. n=52

3. Discussion

To the best of our knowledge, this study represents the first randomized trial to demonstrate the efficacy of curcumin and honey in alleviating cough symptoms among patients with lung cancer. The natural medicine combination of curcumin and honey exhibited notable improvements in cough severity and impact, as indicated by a significant reduction in both parameters and further validated by the cough domain of the CVAS. Alex Massarottis emphasized that tailored symptomatic treatments hold promise for alleviating cough symptoms in adult lung cancer patients.³ Amelie Harle et al. indicated that patients undergoing anticancer treatment experience a lower cough prevalence (40%) compared to untreated patients (54%). Notably, half of the patients considered their cough significant enough to warrant treatment.³ Our study corroborated that there was cough. Baseline control arm showed 7.7% severe cough and 92.3% moderate cough and experimental arm exhibited 38.5% severe cough and 61.5 moderate cough. Tsai et al., demonstrated curcumin's efficacy in inhibiting the metastatic potential of non-small cell lung cancer (NSCLC) cells through modulation of the adiponectin /NF-Kb/MMPs pathway and down regulation of COX- 2 and EGFR with curcumin has stated the efficacy of curcumin .

Kumaravel Mohankumar et al. (2021) conducted a study on the anticancer potential of bis-dimethoxy curcumin (BDMC-A) in

laryngeal cancer. Dimethoxy curcumin acts as a metabolite, an antineoplastic agent, and an anti-inflammatory agent. Same with our study which demonstrated a significant reduction in CVAS score of day 1 to day 22 of the experimental group with a p value of <0.05 indicating the efficacy of curcumin, honey combination. Our study concluded that curcumin and honey offer a new natural therapeutic option for patients with lung cancer and cough, demonstrating efficacy without adverse events.

Shadkam et.al.conducted a clinical experimental study on children aged 2-5 years, revealing that administering honey before bedtime had a beneficial effect on cough associated with upper respiratory tract infections. In our study, a comparison between both arms indicated statistically significant differences in CVAS scores, reinforcing the positive impact of curcumin and honey. In our study in experimental group the moderate cough was 40.0 % which has reduced to 23.5% on 22nd day and the severe cough reduced from 83.3% to 3.3%.

Morrison E.J. et al. asserted that cough is a prominent symptom in lung cancer, often accompanied by emotional issues. Their extensive study, encompassing 2205 participants, revealed that emotional problems were more prevalent in younger individuals, males, current smokers, and those with advanced disease stages. In our study, we observed that a majority of participants (34.61%)

fell within the 31-40 age group, followed by 15.28% in the 18-30 and 41-50 age groups. Participants in the 51-60 age group constituted 23.07%, while the least (11.53%) were in the 61-65 age group. Additionally, 80.76% were male, and 19.24% were females. Monthly income distribution showed that 38.46% had incomes below Rs. 10,000, 34.61% fell in the Rs. 10,001-20,000 range, 15.38% in Rs. 20,001-30,000, 7.69% in 30,001-40,000, and 3.84% with incomes exceeding Rs. 40,000. Furthermore, 84.61% of participants had social habits, such as chewing tobacco, smoking cigarettes and consuming pan masala, while 19.24% reported no social habits. The overarching conclusion from this study is that curcumin and honey represent an effective intervention for cough in lung cancer patients, supported by an open-label randomized control trial with 26 participants. The study involved a treatment regimen using 5 ml of honey and 500 mg of curcumin, with assessment conducted on day 1, 10 and 22 using the cough visual analogue scale (CVAS). Notably, no adverse events were reported during the study period.

4. Conclusion

Curcumin and honey has yielded a good reduction in cough on day 22 with a p value <0.05 in [patients of ca lung. This shows that the intervention was effective [28].

COI – There was no conflict of interest with any authors.

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