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Original Article

Verification of Self-reporting Smoking Status by Urine Cotinine Levels in Patients of Chronic Obstructive Pulmonary Disease

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Abstract

Background: Smoking is invariably one of the most common risk factors for chronic obstructive pulmonary disease (COPD). Self-reporting is the most common mode to ascertain the smoking status but it appears to be less dependable hence a need for a non-invasive marker like urine cotinine levels for determining the actual smoking status.

Materials and Methods: The cross-sectional study was conducted among 55 COPD patients ≥40 years attending the chest clinic and OPD in the Department of Medicine at UCMS & GTB Hospital, Delhi. Detailed history and clinical examination were done and CAT symptom score was calculated. Urine sample was collected to estimate the urine cotinine levels.

Results: The mean age was 61.22 years. About 89.1% (49) were male and 10.9% (6) were female. About 21.8% (12) of the participants had COPD Stage A, 29.1% (16) had Stage B, 1.8% (1) had Stage C, and 47.3% (26) had Stage D; mean urine cotinine was 48.25 ng/mL. About 65.5% (36) of cases biochemically verified to be smoking were non-smoker by self-reporting. Misreporting was 27.3% in the lower-middle class, 72.7% in upper-lower class, and 81.3% in the lower class. Disagreements between self-reported smoking status and urine cotinine-verified status were as follows – Stage A: 41.7%, Stage B: 56.2%, Stage C: 100%, and Stage D: 84.6%. Biochemically verified smoker's group had the larger proportion of participants with a history of hospital admission and was associated with higher GOLD COPD stage. The mean of CAT score was 12.95.

Conclusion: Urine cotinine level can be used as a reliable marker to verify the smoking status in the patients for proper management of COPD patients.

Key words: CAT score, Chronic obstructive pulmonary disease, Self-reported smoking, Urine cotinine

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is an underdiagnosed, progressive, and incurable lung disease characterized by persistent reduction in airflow. This is due to the abnormal inflammatory response of the lung to noxious particle and gases.[1] The substance in tobacco smoke, in particular, alkyl, alkenyl, peroxyl, and organic free radicals, causes lipid peroxidation in plasma and organelle membranes, leading to alteration in structure and membrane permeability and extensive membrane damage.[1,2]

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Smoking cessation is a major and a cost-effective measure improving survival. Smoking cessation slows down the decline in the forced expiratory volume of air expelled in one second (FEV_1). It restores the annual decline of breath capacity to a level approaching normal: The annual decrease of FEV_1 is ~30 ml/year for a non-smoker, ~ 31 ml/year for an ex-smoker and ~ 62 ml/year for a smoker.[3] In addition, smoking cessation reduces bronchial bacterial colonization and allows some recovery of the body's natural defenses, which, in turn, reduces the risk of aggravation. Finally, smoking cessation improves the effectiveness of medication, especially corticosteroids.[4]

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A major step in promoting smoking cessation is to first identify the true smoking status of the patients. Self-reporting of the true smoking status has been found to be grossly underreported so a biochemical marker needs to be used to validate the reporting, cotinine being the most preferred.[5,6] Cutoff values to biochemical verify smokers from non-smokers which vary between 31.5 and 550 ng/ml.[7,8]

COPD assessment test score (CAT) is a simple questionnaire to quantify the impact of COPD symptoms on the health status of the patients. It is positively correlated with severity of airflow limitation and is a good essay for evaluating the severity of disease, management of patient response to treatment, and prognosis.[9,10]

This study was conducted to validate the self-reported smoking status in COPD patients using urine cotinine levels and to correlate the urine cotinine levels with the CAT score.

MATERIALS AND METHODS

Study Setting

The study was conducted at the Department of Medicine and Department of Biochemistry at UCMS and Guru Teg Bahadur Hospital, Delhi.

Duration of Study

The study was conducted from November 1, 2019, till October 31, 2021.

Study Design

This was a cross-sectional study.

Inclusion Criteria

Patients of COPD of age ≥40 years were included in the study.

Exclusion Criteria

Subjects with the following conditions were excluded from the study:

1. Patients using other nicotine containing products (gutka, kaini, etc.) or nicotine replacement therapy
2. Known case of any kidney disease or clinically having symptoms and sings suggestive of kidney disease
3. Patients not willing to participate.

Sample Size

According to a published study, 47% of COPD patients had disagreement between the self-reported smoking status and that determined on the basis of the urinary cotinine concentration. According to the above estimate, taking into account, a relative error of 10% and confidence interval of 95%, sample size calculated was 433 COPD patients but because of time and resource constraints, sample size was estimated to be 90. However, due to COVID pandemic and halting of regular OPD, enrolment of patients was not feasible for long duration. Hence, due to this situation, sample size was reduced to 55.

Methodology

Fifty-five COPD patients ≥40 years of either sex in medicine department were enrolled for the study. Participants were evaluated with detailed history, examination to rule out the patients having kidney disease and to find the CAT symptom score. More than 50 ng/ml was taken as the cutoff of urine cotinine to identify current smokers.

Consent and Ethics

Written and informed consent was taken and institutional ethical clearance was taken.

Specimen Collection Transport and Processing

Urine specimen

Ten milliliters sample of urine sample was collected in sterile container and appropriately labeled. It was stored at biochemistry department laboratory where it was stored at −80°C. After collecting the required samples, ELISA test was performed on the batch samples to estimate the urine cotinine levels.

Statistical Analysis

Data were entered into Microsoft Excel spreadsheet and after cleaning will be analyzed using SPSS software v 20.0. Continuous variables such as cotinine levels, age, and others were presented as mean ± standard deviation (SD); whereas, categorical variables such as accuracy of self-reported smoking status with respect to urine cotinine levels, severity status of COPD, etc., was presented as absolute and relative frequencies. The accuracy status of the self-reported smoking status among different sociodemographic groups, across various severity status of COPD was reported. The strength of correlation between urine cotinine levels and CAT score was assessed by Pearson's correlation coefficient. All tests were two tailed and $P = 0.05$ was considered as statistically significant.

RESULTS

The mean age was 61.22 years with SD of 8.11 among 55 patients enrolled in this study. About 89.1% (49) of the participants were male while 10.9% (6) of the participants were female. The mean smoking pack-year was 27.24. About 45.5% (25) of the participants had a history of ≥1 hospital admission while 54.5% (30) of the participants had no history of hospital admission. About 21.8% (12) of the participants had COPD Stage A. About 29.1% (16) had COPD Stage B. About 1.8% (1) had COPD Stage C.

About 47.3% (26) had COPD Stage D. The mean (SD) of CAT score was 12.95 [5.87]. Among different components of CAT score, breathlessness had maximum mean [SD] severity of 3.05 [1.06] while chest tightness had minimum mean severity of 0.53 [0.69].

The mean (SD) of urine cotinine (ng/mL) was 48.25 (22.06). The urine cotinine (ng/mL) ranged from 0.77 to 67.03.

About 3.6% (2) of the participants self-reported the smoking history while 96.4% (53) of the participants did not self-report.

As shown in Table 1, using 50 ng/ml as urine cotinine cutoff, 67.3% (37) of the participants were classified as smoker and 32.7% (18) of the participants were classified as non-smoker based on urine cotinine-verified results. About 3.6% (2) of the participants had self-reported to be currently smoking while 96.4% (53) of the participants had self-reported as not smoking.

The disagreements observed between the two methods were as follows: 65.5% (36) of cases classified to be smoker by urine cotinine were self-reported to be non-smoker. About 1.8% (1) cases classified as non-smoker by urine cotinine were reported as smoker by self-reporting. The two methods agreed in 32.7% of the cases and disagreed in 67.3% of the cases. There was poor disagreement between the two methods, and this agreement was not statistically significant (Cohen's kappa = −0.019, $P = 0.596$).

In this study, disagreements between self-reported smoking status and urine cotinine-verified status within different stages of COPD were as follows – Stage A: 41.7% (5), Stage B: 56.2% (9), Stage C: 100% (1), and Stage D: 84.6% (22), as shown in Table 2. There was a statistically significant difference between the various groups in terms of distribution of misreporting ($\chi^2 = 8.495$, $P = 0.025$). Fisher's exact test was used to explore the association between "misreporting" and "COPD stage" as more than 20% of the total number of cells had an expected count of less than 5.

As shown in Table 3, misreporting of smoking status according to modified Kuppuswamy scale was as follows: 27.3% (3) in the lower-middle class, 72.7% (16) in upper-lower class, and 81.8% (18) in the lower class. Chi-squared test was used to explore the association between "misreporting" and "Modified Kuppuswamy Scale." There was a statistically significant difference between the various groups in terms of distribution of misreporting ($\chi^2 = 10.405$, $P = 0.006$).

In this study, biochemically verified smoker's group had 59.5% (22) of the participants with a history of hospital admission and 40.5% (15) did not have a history of hospital admission. Biochemically verified non-smoker's group had 16.7% (3) of the participants with a history of hospital admission and 83.3% (15) of the participants had no history of hospital admission, as shown in Table 4. There was a statistically significant difference between the various groups in terms of distribution of hospital admission ($\chi^2 = 8.944$, $P = 0.003$).

Biochemically verified smokers (patients with urine cotinine >50 ng/ml) were found to be distributed as follows: 10.8% (4) in COPD Stage A, 24.3% (9) of the participants in COPD Stage B, 2.7% (1) of the participants in COPD Stage C, and 62.2% (23) of the participants in COPD Stage D. Biochemically verified non-smokers (patients with urine cotinine ≤50 ng/ml) were found to be distributed as follows: 44.4% (8) in COPD Stage A, 38.9% (7) in COPD Stage B, 0% of the participants COPD Stage C, and 16.7% (3) of the participants in COPD Stage D. There was a statistically significant difference between the various groups in terms of distribution of COPD stage ($\chi 2 = 12.950$, $P = 0.002$). Biochemically verified smokers/those continuing to smoke were associated with higher GOLD COPD stage, as shown in Table 5.

Table 1: Comparison of smoking status (self-report) with smoking status (urine cotinine)

Smoking status	Smoking status (urine cotinine) (%)			Cohen's kappa	
	Yes	No	Total	k	*P*-value
Smoking status (self-report)					
Yes	1 (1.8)	1 (1.8)	2 (3.6)	–0.019	0.596
No	36 (65.5)	17 (30.9)	53 (96.4)		
Total	37 (67.3)	18 (32.7)	55 (100.0)		

Table 2: Association between misreporting of smoking status and COPD stage

COPD stage	Misreporting (%)			Fisher's exact test	
	Yes	No	Total	χ^2	*P*-value
A	5 (41.7)	7 (58.3)	12 (100.0)	8.495	0.025
B	9 (56.2)	7 (43.8)	16 (100.0)		
C	1 (100.0)	0 (0.0)	1 (100.0)		
D	22 (84.6)	4 (15.4)	26 (100.0)		
Total	37 (67.3)	18 (32.7)	55 (100.0)		

Table 3: Association between misreporting of smoking status and modified Kuppuswamy scale

Modified Kuppuswamy scale	Misreporting (%)			Chi-squared test	
	Yes	No	Total	χ^2	*P*-value
Lower-middle	3 (27.3)	8 (72.7)	11 (100.0)	10.405	0.006
Upper-lower	16 (72.7)	6 (27.3)	22 (100.0)		
Lower	18 (81.8)	4 (18.2)	22 (100.0)		
Total	37 (67.3)	18 (32.7)	55 (100.0)		

Table 4: Study of association between urine cotinine-verified smoking status and history of hospital admission (*n* = 55)

History of hospital admission	Urine cotinine-verified smoking status (%)			Chi-squared test	
	Yes	No	Total	χ^2	*P*-value
Yes	22 (59.5)	3 (16.7)	25 (45.5)	8.944	0.003
No	15 (40.5)	15 (83.3)	30 (54.5)		
Total	37 (100.0)	18 (100.0)	55 (100.0)		

Table 5: Study of association between urine cotinine-verified smoking status and COPD stage

COPD stage	Urine cotinine-verified smoking status (%)			Fisher's exact test	
	Yes	No	Total	χ2	*P*-Value
A	4 (10.8)	8 (44.4)	12 (21.8)	12.950	0.002
B	9 (24.3)	7 (38.9)	16 (29.1)		
C	1 (2.7)	0 (0.0)	1 (1.8)		
D	23 (62.2)	3 (16.7)	26 (47.3)		
Total	37 (100.0)	18 (100.0)	55 (100.0)		

DISCUSSION

This was a cross-sectional study conducted among COPD patients attending the chest clinic and OPD in the Department of Medicine at UCMS & GTB Hospital, Delhi, for a regular check-up and follow-up in which urine was taken as a sample to verify the self-reported smoking status which was obtained non-invasively and rapidly. The aim of this study was to verify self- reported smoking status in patients of COPD using urine cotinine levels and to correlate urine cotinine levels with CAT score**.** Although this study has been done abroad, similar study has not been done in COPD patients in India or Indian population.

In this study, the mean age (years) was 61.22 ± 8.11. The age ranged from 40 to 87 years. About 69% of the participants were above the age of ≥60 years. About 89.1% (49) of the participants were male and rest were female. The mean urine cotinine (ng/mL) was 48.25 ± 22.06.

About 3.6% (2) of the participants had reported smoking status as "Yes." About 96.4% (53) of the participants had declared their smoking status as "No."

The Calbiotech ELISA method for urine cotinine estimation recommends a cutoff value of >50 ng/ml. A study done by Balhara *et al.* for verification of self-reports of the use of tobacco products also used a cutoff of >50 ng/ml by ELISA method.[11] Therefore, in this study, the results were based on urine cotinine cutoff >50 ng/ml to biochemically verify smoking status.

About 67.3% (37) of the participants had urine cotinine more than the cutoff and were categorized as smokers whereas 32.7% (18) of the participants had urine cotinine less than the cutoff and were categorized as non-smokers. The two methods agreed in 32.7% of the cases and disagreed in 67.3% of the cases.

The disagreements observed between the two methods using >50 ng/ml urine cotinine as cutoff were as follows: 65.5% (36) of cases biochemically verified to be smoking were reported not to be smoking by self-reported smoking status. About 1.8% (1) of cases biochemically classified as non-smoker had reported to be smoking during self-reports.

The diagnostic performance of smoking status (self-report) in predicting actual smoking status (urine cotinine) was as follows: Sensitivity: 2.7%, specificity: 94.4%, positive predictive value: 50%, and negative predictive value: 32.08% with diagnostic accuracy: 32.73%.

Misreporting was maximum (81.3%) in the lower class according to modified Kuppuswamy scale. Participants in the lower class had the largest proportion of misreporting/ disagreement between self-reported smoking status and urine cotinine-verified smoking status. Participants in the lower middle had the largest proportion of agreement between self-reported smoking status and urine cotinine-verified smoking status. It was observed that the higher socioeconomic class had lesser disagreement between self-reported and urine cotinine-verified smoking status in this study, statistically significant difference was observed between the various groups in terms of distribution of misreporting.

In the study by Kim *et al.* among Korean male adults, it was found that the ratio of cotinine-verified status to self-reported status tended to be greater in the groups with educational level and low household income although this correlation was not statistically significant.[12]

In this study, it was observed that patients with higher GOLD COPD stages such as C and D have more disagreement between self-reported and urine cotinine-verified smoking status as compared to GOLD COPD Stages A and B.

In the study done by Hilberink *et al.*, a cross-sectional smoking status validation study was conducted in 60 patients with COPD who initially reported that they had stopped smoking. In the analysis of urine samples, a cutoff point of 50 ng/mL of cotinine was used. About 72% (43) of patients out of 60 patients were classified by the urine cotinine test as non-smokers (median cotinine

level 13.0 ng/mL) while 28% (17) were classified as smokers (median cotinine level 134.0 ng/mL). During the time of the biochemical validation, 12 of the 17 patients, who were classified as smokers, reported that they did not and five said that they had smoked. Twelve patients (22%) out of 55 self-reported non-smokers were classified as smokers; thus, there was misreporting by 22% of patients.[13]

In a study done by Monninkhof et al. on COPD outpatients, it was found that patients were biochemical classified as smokers if their salivary cotinine level exceeded 20 ng/ml. At baseline out of total 188 patients, 118 self-reported as not smoking, 13.5% (16) of reported non-smokers had cotinine value more than cutoff. After 9 months of smoking cessation program, out of the 63 patients who took part and were followed, 23 patients reported abstinence but 52% (12) of these had cotinine value more than cutoff.[14]

In a cross-sectional study by Nuca *et al*. of 286 participants aged 35–44 years, the unstimulated salivary cotinine levels were measured using the NicAlert™ saliva test (Jant Pharmacal Corporation, Encino, CA, USA) with Level 0 interpreted as non-smokers, Levels 1–2 interpreted as occasional smoker, and 3–6 interpreted as active constant smokers. Of the self-reported 160 non-smokers, 113 participants had saliva cotinine in Levels 1–6, 10 self-reported occasional smokers, and 116 self-reported current constant smokers had saliva cotinine in Levels 1–6. There was a disagreement of 41% in self-reports and saliva cotinine results.[15]

In a study, Paci *et al*. done on 1075 inhabitants of Central Italy about the self-reported smoking status with urine cotinine cutoff of ≥100 μg/g creatinine. According to the questionnaire, there were 275 smokers, but six of these present urinary cotinine levels lower than the cutoff, giving a 2.2% misclassification rating; 800 subjects declared to be non-smokers, but 26 of them present urinary cotinine levels higher than the cutoff (3.3%).[16]

In prevention of renal and vascular end-stage disease (PREVEND) a prospective cohort study by Kunutsor *et al*. on 4737 patients with mean age of 53 years. About 45.5% were men. The mean (SD) of urine cotinine was 370 (721) ng/mL. The cutoffs for urine cotinine were <100 ng/ml, 100–500 ng/ml, and 500 ng/mL for the categories of never smokers, former smokers, and current smokers, respectively. Of the 1458 self-reported never smokers, 8 (0.5%) had urine cotinine concentrations consistent with active smoking; and of the 1997 self-reported former smokers, 53 (2.7%) had urine cotinine concentrations consistent with active smoking. Hence, the misclassification rate of active smokers (the number of misclassified active smokers divided by the number of self-reported active smokers 40) was 4.8%. Furthermore, of the 3407 never smokers as assessed by urine cotinine concentrations, a majority (1887, 55.4%) were classified as former smokers by self-reports.[6]

This study suggests that patients with COPD commonly provide misinformation regarding their smoking status. In this study, there was a higher self-misreporting rate on verification by urine cotinine. The possible reasons are increased proportion of participants of age >60 years, participants with low education level, low household income, and history of multiple previous visits. Analyses according to a study by Kim *et al*. showed that age older than 60 years, educational level of high school graduation or lower, multiple health check-ups, and urine cotinine levels <500 ng/mL were associated with a higher discrepancy between self-reporting and cotinine-verified smoking status rates which can explained due to face-to-face interviews which have been shown to be related to underreporting in smoking whereas paper surveys are deemed more accurate probably due to the sense of anonymity that it provides.[12]

About 1.8% of participants whose urine cotinine was lower than 50 ng/mL reported that they were currently smoking. Since the half-life of cotinine is about 18 h, it may not be detected in those who did not smoke 2 or more days before sample collection or in those attempting cessation of smoking. It was found in a study by Rebagliato that about half of the self-reported occasional smokers had cotinine values lower than cutoff.[17]

Similar discrepancy of self-reported status as smoker and urine cotinine less than the cutoff was seen in a study done in India on 131 psychiatric outpatients (male) with a mean age of 31.05 years by Balhara *et al*., with a urine cotinine cutoff of >50 ng/ml in which out of 107 self-reported non-smokers, 60 subjects have urine cotinine levels more than cutoff and 13 out of 24 self-reported smoker had urine cotinine levels less than cutoff. About 55.7% of the total self-reported smoking status was in disagreement with urine cotinine levels.[11]

In this study, the mean CAT score was 12.95 ± 5.87. There was a weak positive correlation between urine cotinine and CAT score and the correlation was not found to be statistically significant. The correlation coefficient (rho) between the two was 0.24 and p =0.079 was considered. According to a cross-sectional study by Karadogan *et al*. in 117 COPD patients in Turkey, it was found that current smokers are more likely to have a higher CAT score and higher CAT scores were associated with current smoking.[18] Our result of a weak positive but not statistically significant correlation could be due to less sample size.

It was also observed in our study that biochemically verified smoker's group had the statistically significant larger proportion of participants with a history of hospital admission. Biochemically verified non-smoker's group had the larger proportion of participants with no history of hospital admission. Hence, COPD patients who are continuing to smoke are more likely to be hospitalized than those who have stopped smoking.

Biochemically verified smokers/those continuing to smoke were statistically significantly associated with higher GOLD COPD stage and biochemically verified non-smokers were associated with lower GOLD COPD stage in this study. So, continued smoking likely to increase the severity of COPD.

CONCLUSION

Urine cotinine levels are an important marker which can be used to denote and verify the actual smoking status in patients of COPD which can further help in proper diagnosis, staging the severity, proper assessment for the treatment and follow-up, and help in counseling and advising preventive therapy to reduce the hospital admissions and mortality.

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