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APPENDIX A6.1.4.13 FORCED EXPIRATORY VOLUME IN ONE SECOND (FEV1)

HEALTH EFFECTS OF SMOKING CESSATION

Short Term Health Effects

Forced expiratory volume in one second (FEV1)

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Version: 4.0

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1 BACKGROUND

Spirometry is used universally to assess lung function and is recommended in the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines (1) as well as national guidelines (2), to be the gold standard for accurate and repeatable measurement of lung function. It is a valuable tool for clinicians in the diagnosis, management and monitoring of a variety of respiratory conditions. However, the quality of spirometry tests are crucially dependent on the operator and cooperation of the patient and thus spirometry performed in primary care is often of poor quality (3) and even in countries where spirometry is in more common usage, there are major concerns regarding the technical ability of operators to perform the test and interpret its results. Many primary care physicians , nurses, and other health care providers have had little formal training in spirometry.The most common parameters measured in spirometry are the Forced Expiratory Volume (FEV) at timed intervals of 0.5, 1.0 (FEV_1), 2.0, and 3.0 seconds as well as Forced Vital Capacity (FVC). Other measured parameters include Forced Expiratory Flow 25–75% (FEF 25–75) and maximal (mid) expiratory flow (MMEF or MEF). FEV_1 values are presented as raw data (liters or liters per second) or as percent predicted (FEV_1 % predicted) in which the test result is presented as the percentage of the predicted value for individuals of similar characteristics including height, age, sex, race and weight. Lung function is considered normal if the FEV_1 is within 80% to 120% of predicted values. In healthy adults the FEV_1/FVC ratio (or Tiffeneau-Pinelli index (4)) should be approximately 75–80%. In obstructive pulmonary diseases (asthma, COPD, chronic bronchitis, emphysema) FEV_1 is diminished because of increased airway resistance to expiratory flow. FEV_1 can only decline over years; in healthy non-smokers, this decline is estimated to be 30mL/year (3).Airway diseases are strongly related to cigarette smoking. Although generally estimated around 15%, it is likely that 50% of smokers will develop chronic obstructive pulmonary disease (COPD) (5). While less common than in smokers, a percentage of non-smokers also develop COPD. In the United States, 20% of those who have low lung function and 20% of those who die of COPD are non-smokers (5). It is also clear that there are genetic factors that account for the varying susceptibility of smokers to develop COPD.FEV_1 is a reliable spirometric parameter that reflects the physiological state of the lungs and airways. FEV_1 normally decreases with age, and the rate of fall is an important spirometric indicator of disease progression in COPD. In healthy non-smoking adults the decrease is about 30 mL/year with an upper limit of about 50 mL/year (3). There is no single fixed cut-off for FEV_1 to confirm the presence of airflow obstruction, because the lower limit of normal decreases with age. FEV_1 is used as a marker of disease severity, but its role as a surrogate endpoint for treatment effect is not clear.The aim of the present research was to identify published work relating to FEV_1 as a biomarker of airflow obstruction relating to smoking conventional cigarettes, the effects of smoking and smoking cessation on the levels of the biomarker and its relationship to CVD and respiratory diseases.

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2 METHODS

Three searches of the PubMed literature data base were conducted on March 13th, 2015 for English language articles within the time frame of 2008 to the present day.

Search 1: To identify literature that linked smoking or nicotine replacement to FEV1 using the search string: (forced expiratory volume OR FEV) AND (smokers OR smoking OR nicotine replacement OR cessation) AND ("2008"[Date - Publication]: "2015"[Date - Publication]) AND English[Language].

Search 2: To identify literature reporting an association between FEV1 and cardiovascular disease using the search string: (forced expiratory volume OR FEV1) AND ((cardiovascular disease) AND (association)) AND ("2008"[Date - Publication]: "2015"[Date - Publication]))) AND English[Language]).

Search 3: To identify literature reporting an association between FEV1 and respiratory disease using the search string: (forced expiratory volume OR FEV1) AND ((respiratory disease) AND (association)) AND ("2008"[Date - Publication]: "2015"[Date - Publication]))) AND English[Language]).

Among the identified studies a set of specific criteria was applied to determine which papers should be selected for inclusion within the report.

The following inclusion criteria were applied:

- Studies investigating the association of cigarette smoking, smoking cessation or nicotine replacement therapy (NRT) on FEV1
- Studies investigating the association of FEV1 with cardiovascular disease or respiratory disease

The following exclusion criteria were applied:

1. Studies that used the measurement of FEV1 simply for control purposes (e.g., results were adjusted for differences in FEV1 between populations, but FEV1 itself was not an endpoint)
2. Studies involving dietary, pharmacological or exercise interventions in which FEV1 was an endpoint, but lacking a clear link between FEV1 and either a disease of relevance or smoking
3. Studies in patients with a disease not covered by the search categories (e.g., cancer, HIV infection, periodontitis) where there was no clear link between FEV1 and either a disease of relevance or smoking
4. Studies of passive or parental smoking
5. Studies showing a link between FEV1 and either a disease of relevance or smoking, but in a defined, narrow population (e.g., pregnant women, individuals with a particular haplotype, individuals with a specific disease) or tissue (e.g., retina, gums)

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6. Studies reporting results from in vivo animal experiments
7. Studies in which FEV1 was measured for toxicological or forensic purposes
8. Studies with no comparison between smoking and non-smoking/switching/cessation
9. FEV1 not measured or presented as AUC

3 FINDINGS

Searches 1, 2 and 3 produced 1581, 19 and 724 articles respectively. From the 2324 references identified, 398 were common to 2 or 3 searches, leaving 2305 unique references, of which 19 were considered for inclusion (see Table 1).The literature searches identified 19 articles that met the inclusion and exclusion criteria: 13 smoking-related studies (smokers vs non-smokers vs ex-smokers: (6), (7), (8), (9), (10), (11), (12); smokers vs non-smokers : (13), 4 smoking-related reviews or meta-analyses [(14), (15), (16), (17)], 1 heart-disease study which was described in 2 articles [(18), (19)], and 3 general articles about FEV_1 or respiratory diseases [(3), (5), (20)]. The information from these articles was used in the preparation of this document with the exception of the article by Kohansal, 2009 (6), the data from which was already included in a meta-analysis (16) thus the article was kept in the reference list, but not presented separately.The reasons for the exclusion of articles from the review are described below in Table 1 which provides an overview of the results from the three searches together with the reasons for exclusion.

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Table 1 Search results and distribution across the exclusion criteria.

Search	1	2	3	Total
Number of different articles retrieved	1581	19	724	2324
Articles discarded due to:				
E1: FEV_1 used only as marker of exposure	380	1	166	547
E2: FEV_1 lacked link to smoking	152	6	94	252
E3: Disease not covered by search categories	450	8	245	703
E4: Passive or parental smoking	19			19
E5: Narrow population	55	1	151	207
E6: Animal	4		1	5
E7: FEV_1 measured for forensic purposes	1			1
E8: No comparison to smoking and cessation or switch	416	2	38	456
E9: FEV_1 not measured	85	1	29	115
Total discarded	1562	19	724	2305
Articles selected	19			19

The 2,324 articles retrieved by the three searches are listed in Appendix 1-Appendix 4 with those excluded according to the above selection/exclusion criteria grouped related to their reason for exclusion (E1 – E9).

4 BIOMARKER-DISEASE LINK

The searches retrieved no literature reporting short-term links between FEV_1 and cardiovascular or respiratory diseases.

4.1 Cardiovascular disease

FEV_1 is normally not a marker used independantly in cardiovascular diseases but in association with an obstructive pulmonary disease. Cardiovascular disease is the most common cause of death in patients with chronic obstructive pulmonary disease (COPD), and a major comorbidity in COPD, especially atrial fibrillation and heart failure. Roughly 30% of patients with stable COPD will have some degree of heart failure, with FEV_1 being a strong predictor of mortality, and COPD patients have an increased incidence of atrial fibrillation (21).

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Two articles were retrieved, relating two different outcomes in the same Atherosclerosis Risk in Communities (ARIC) cohort, which had a median follow-up of 17 years. Relative to heart failure (18), the multivariable adjusted incidence of failure was higher in those with $FEV_1/FVC<70\%$ vs. $\geq 70\%$: hazard ratios were 1.44 (95%CI 1.20–1.74) among men and 1.40 (1.13–1.72) among women. The authors concluded that spirometry seems to be worth considering for all patients admitted with HF in order to identify patients at high risk. The rate of incident atrial fibrillation (AF) was inversely associated with FEV_1 (19): hazard ratios (95% confidence intervals) of AF comparing the lowest with the highest quartile of FEV_1 were 1.37 (1.02-1.83) for white women, 1.49 (1.16-1.91) for white men, 1.63 (1.00- 2.66) for black women, and 2.36 (1.30-4.29) for black men. The above associations were observed across all smoking status categories. Moderate/severe airflow obstruction ($FEV_1/FVC<0.70$ and $FEV_1< 80\%$ of predicted value) was also associated with higher AF incidence. Mild to moderate pulmonary hypertension (PH) is a highly prevalent complication of COPD, caused by vasoconstriction and remodelling of pulmonary arteries. PH prevalence reaches 50% in advanced COPD, without altering right ventricular function in the majority of patients. However 1-3% patients will present out-of-proportion PH, with pulmonary arterial pressure largely exceeding the severity of airway impairment (22). Recognition of PH can be difficult because symptoms are not easy to differentiate from the clinical picture of COPD. Suspicion of PH should be high if clinical deterioration is not matched by the decline in pulmonary function, and in the presence of profound hypoxaemia or markedly reduced carbon monoxide diffusing capacity. Patients with suspected PH should be evaluated by Doppler echocardiography and, if confirmed, undergo right-heart catheterization to determine clinical management (22).

4.2 Respiratory disease

FEV_1 is commonly used as a diagnostic test or a marker for progression of obstructive respiratory diseases, hence the number of articles retrieved by the searches. However, all relevant findings relative to FEV_1 and respiratory diseases are gathered in international guidelines and general or systematic reviews.The major characteristic of chronic obstructive respiratory disease (COPD) is the presence of chronic airflow limitation that progresses slowly over a period of years and is, by definition, largely irreversible. COPD is heterogeneous, progresses slowly and variably and is often diagnosed relatively late in its course (5). The standard respiratory function test for case detection of chronic obstructive pulmonary disease (COPD) is spirometry. In the Global Initiative on Obstructive Lung Disease (GOLD) guidelines (21), the criterion for diagnosis definition is based on a post-bronchodilator $FEV_1/FVC < 0.70$ and COPD severity is based on FEV_1:

- mild (GOLD 1) FEV1 ≥ 80% predicted,
- moderate (GOLD 2) 50% ≤ FEV1 < 80% predicted,
- severe (GOLD 3) 30% ≤ FEV1 < 50% predicted,
- very severe (GOLD 4) FEV1 < 30% predicted

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The annual decline in FEV_1 is a marker of disease progression and changes in FEV_1 could be a marker for long-term treatment effect (14). However, there is a striking heterogeneity among patients with COPD, with poor correlations between FEV_1, symptoms, quality of life, functional outcomes, and biomarkers (20). In the Evaluation of COPD Longitudinally to Identify Predictive Surrogate Endpoints (ECLIPSE) study (14), the decline in FEV_1 was less than anticipated (i.e. 33 mL/year, as compared to 30mL/year in healthy non-smokers (3), and showed an marked variability [(14), (15)]. The poor relationship between the severity of airflow limitation (FEV_1) and several clinically relevant domains of COPD seems to exclude FEV_1 from useful relevant biomarkers.In asthma spirometry is considered for a more confident diagnosis and for predicting risk. According to the Global Initiative for Asthma (GINA) guidelines (23), measurements of lung function to confirm airflow limitation, and particularly the demonstration of reversibility of lung function abnormalities, enhance the confidence in the diagnosis. The degree of reversibility in FEV_1 that indicates a diagnosis of asthma is generally accepted as ≥12% and ≥200 mL increase from the pre-bronchodilator value. However, most patients with controlled asthma will not exhibit reversibility at each assessment, particularly those on treatment, and the test therefore lacks sensitivity. Because many lung diseases may result in reduced FEV_1, a useful assessment of airflow limitation is the ratio of FEV_1/FVC. The FEV_1/FVC ratio is normally >0.75–0.80. Lower values suggest airflow limitation. FEV_1 should be measured at the start of treatment, after 3–6 months of controller treatment to record the patient's personal best lung function, then periodically for ongoing risk assessment. Low initial FEV_1 is a risk factor for exacerbations and for developing fixed airflow limitation (23).

5 SMOKING-BIOMARKER LINK

The link between cigarette smoking and annual decline in FEV_1 is moderate: there is a reduction in FEV_1 with increasing smoking history. For each smoking history, however, there is considerable heterogeneity in FEV_1 response. Even among non-smokers, there is a subset with severe lung function impairment (Figure 1, changes in FEV_1 in two different cohorts, taken from reference (5). As previously stated, because of variability, FEV_1 poorly correlates with smoking or smoking cessation. FEV_1 is commonly used as a marker of disease progression, and should not be considered alone. Several other variables have been shown to be independent markers (5), leading to the development of various indices and to seeking for other more reliable markers (20).

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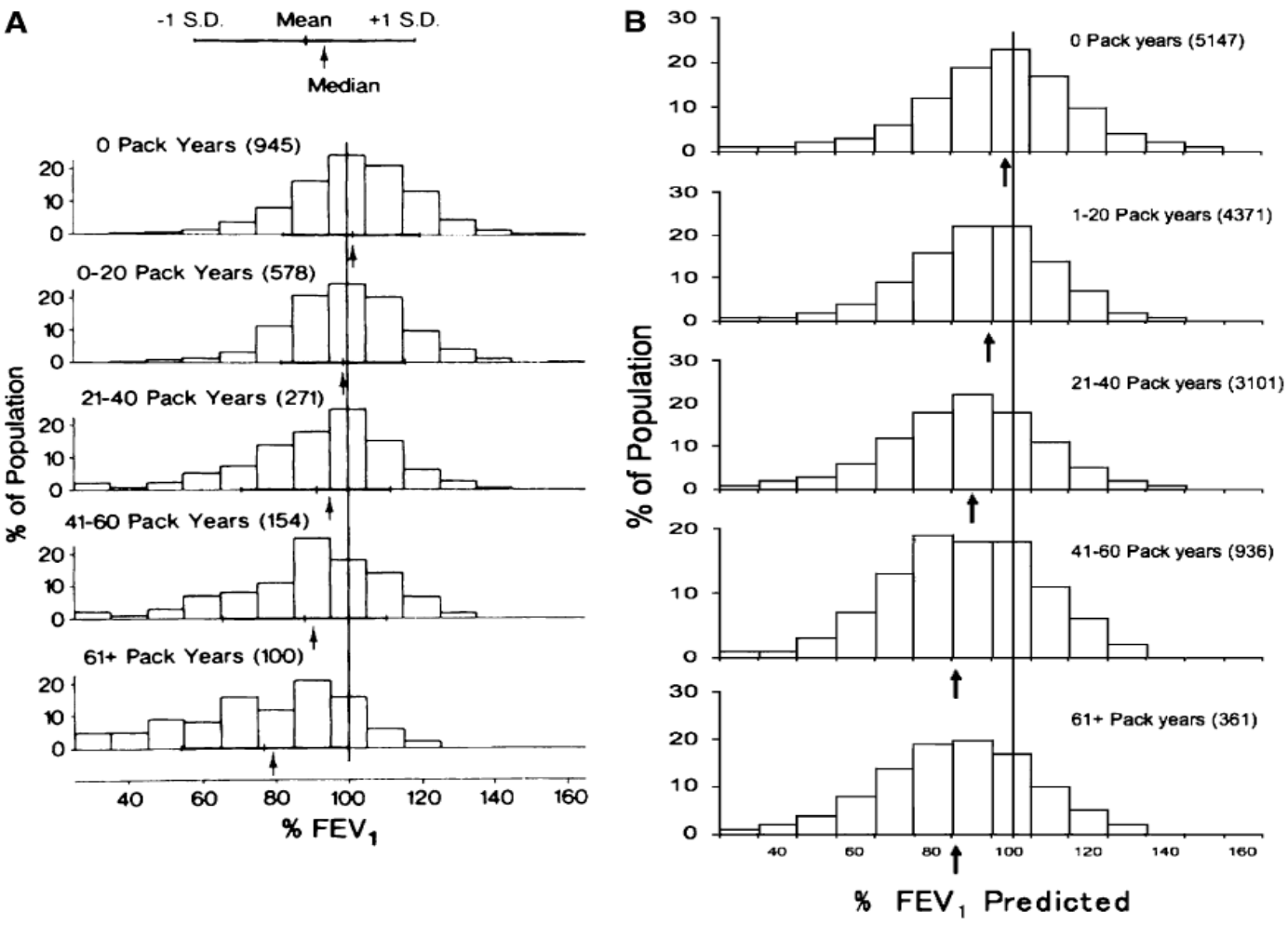


Figure 1 Distribution of FEV1 values in relationship to smoking history (5)

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5.1 Smoking

Table 2 summarizes the articles retrieved from the current literature search, in which smokers were compared to non-smokers with respect to FEV1 changes. One article ((6) Kohansal, 2009), taken into account in the Lee et al. meta-analysis (16), is not included in the table. FEV1 changes are variously expressed as annual decline [(8), (9), (16)], difference from baseline [(13), (11)] or as additional change (increase or decrease) when compared to a reference group [(7), (10), (12)]. Variability of the measure is either provided by 95% confidence intervals (95%CI) or standard error of the mean (SE). The length of follow-up ranged from two years to more than 30 years, except in the Tashkin randomized controlled trial of tiotropium (9) where the follow-up was 52 weeks, and in the Telenga randomized controlled trial of inhaled corticosteroids in asthma patients (11) where the changes in FEV1 from baseline are provided after 2 weeks of treatment. The time elapsed between smoking cessation and FEV1 measurments was not specified.All of the articles in which smokers were compared to non-smokers showed that smoking decreased FEV1 over time, but with great variability, and with changes of small clinical magnitude (Table 2). The larger effect was observed in a study with no non-smoker arm (9), showing a mean annual decline of -23 mL/year for ex-smokers and of -52 mL/year for current smokers. The Lee et al. (16) estimate of annual decline for non-smokers was the closest to the -30mL/year healthy non-smoker estimate (3). In this analysis, there was no difference between ex- and non-smokers, and a dose-related decline in current smokers over 10 mL/year greater than in never smokers, ex-smokers or quitters. The Tang et al. estimates (12) were close to the results presented by Lee et al.

Numbers are difficult to compare across studies, mainly due to FEV1 variability.

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Table 2 Current literature showing annual decline in FEV1 in smokers, non-smokers and ex-smokers/quitters.

Reference	Measure	Smokers	N	Ex-Smokers	N	Non-smokers	N
Clennell (2008) (7)	Additional change* mL/year (95%CI)	-8.44 (-12.21 - 4.68)	894	0.82 (-4.59 - 2.94)	909	Not provided (Reference)	737
Zhou (2010) (8)	Decline mL/year mean (SE) Intervention	-66 (7)	94	-38 (7)	96	-14 (4)	239
	Control	-63 (6)	127	-55 (8)	72	-40 (5)	232
Tashkin (2010) (9)	Decline mL/year mean (SE) Tiotropium	-52 (4)	313	-23 (2)	1486	None	0
	placebo	-52 (4)	303	-23 (2)	1438		
Kotz (2011) (13)	Difference in L from baseline, mean (SE)	-0.058 (0.21)	201	None	0	-0.080 (0.23)	46
Budulac (2012) (10)	Additional change* mL/year (95%CI)	-6.4 (-12.5 - -0.3)	489	1.5 (-5.3 ; 8.4)	456	Not provided (Reference)	445
Lee (meta-analysis) (2013) (16)	Decline mL/year (95%CI)	-42.8 (38.5 - 47.2)	NA	-24.1 (19.2-29.1)	NA	-27.9 (23.5 - 32.4)	NA
Telenga (2013) (11)	Difference in L from baseline, mean (95%CI)	0.08 (-0.05 - 0.32)	19	0.14 (-0.07 - 0.31)	19	0.30 (0.18 - 0.77)	38
Tang (2014) (12)	Additional decline mL/year, mean (SE)	-8.8 (0.7)	NA	-2.3 (0.5)	NA	-26.9 (0.3) (Reference)	NA

NA: not applicable. Several cohorts combined

* Change additional to non-smoker rate of decline. Can be positive (increase) or negative (decrease)

5.2 Smoking cessation

Smoking cessation effects are generally studied in the short and long term, or long term only. In the articles that studied effects on FEV_1 following quitting or switching to a potentially less harmful product, the authors noted an increase in FEV_1 in the short term, i.e., 12 weeks at most, but a decline at one year (Table 3). A great variability in the measurements can be noted again.

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Table 3 Changes in FEV_1 (mL) following quitting/switching.

Reference	Condition	Smoking status	N	Baseline	N	Endpoint	Quitting duration
Jang (2010) (24)	Asthmatic FEV_1 % predicted	Smokers Quitters	22 10	68.2 (2.4) 73.6 (5.6)	22 10	78.4 (5.9) 101.3 (10.1)*	3 months
Tashkin[b] (2011) (25)	COPD FEV_1 change from baseline (mL)	Smokers		Not provided	252 165 155	37.9 (14.0 - 61.9) -19.1 (50.3 - 12.1) -46.3 (-81.3 - -11.4)	12weeks 24 weeks 52 weeks
		Quitters		Not provided	120 76 60	121.8 (85.0 - 158.5)* 58.4 (5.7 - 111.0) -9.6 (-73.4 - 54.1)	12weeks 24 weeks 52 weeks
Pezzuto[b] (2013) (26)	Healthy - FEV_1 % predicted	Reducers Quitters	101 80	86.57 (18.0) 86.57 (18.0)	101 80	87.55 (17.9) 89.15 (17.9)	3 months
Dhariwal (2014) (27)	COPD FEV_1 (L)	Quitters	38	1.59 (1.40 - 1.77)	17 11	+184 mL** -10 mL	6 weeks 1 year
	Healthy[a] FEV_1 (L)	Quitters	55	3.05 (2.84 - 3.25)	33 21	+60 mL -10mL	6 weeks 1 year

Values are mean (SD) except [a]only means: extrapolated from graphical presentation; b: LS means (95%CI)

* statistically significant difference between smokers and quitters

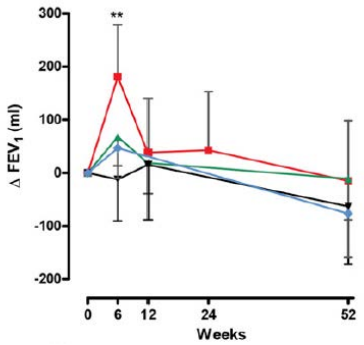
** statistically significant difference from baseline

In addition a review and meta-analysis conducted by PN Lee on 5 large cohort studies analyzed the effect of smoking reduction on various factors including FEV_1 changes (17). Lee concluded that no effect on COPD or on the rate of FEV_1 decline could be established.According to these findings, smoking cessation cannot lead to a sustained improvement of FEV_1, consistent with the findings that cessation has no direct effect on airflow limitaion (5), which does not mean that there is no effect on health status.

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Table 4.Selected studies showing association between smoking, cessation or switching and FEV1 retrieved in the current search.

Source	Country	Period	Design	Study population	Study size (n), sex, age (mean±sem or range)	Comments
Tang (2014) (12)	Multi-national	4-29 yrs FU	Meta-analysis and genome-wide analysis	14 population-based cohorts	27249	Decline in FEV_1: Never smoker: 26.9±0.3 mL/yr; 8.8±0.7, 2.6±0.6, and 2.3±0.5 mL/year steeper in persistent, intermittent, and former smokers
Dhariwal (2014) (27)	UK	? - One year follow-up	Smoking cessation program	COPD and healthy smokers	Smokers COPD 38, 17 quitters at W12; healthy smokers 55, 33 healthy quitters at W12; never 19; M+F, age 40-80 yrs	Subjects with COPD who quit smoking had a marked, but transient improvement in FEV_1 at 6 weeks (184 mL, n = 17, P<.01) that was still present at 12 weeks (81 mL, n = 17, P<.05) but not at 1 year. No results on healthy quitters except graph… red COPD quitters, green healthy quitters, black healthy smokers, blue never smokers 

(table continues)

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Source	Country	Period	Design	Study population	Study size (n), sex, age (mean±sem or range)	Comments
Pezzuto (2013) (26)	Italy	2009 – 2011	Smoking cessation program – NRT + varenicline	Smokers	181; M+F; mean(SD) age 53(5) reducers; 55(1.5) quitters (years)	FEV_1 %pred Reducers Quitters Baseline 86.6 (18.0) 86.6 (18.0) Month 3 87.6 (17.9) 89.2 (17.9)
Telenga (2013) (11)	Netherlands		RCT of ICS; 2 wks trt; 50 wks FU	Asthma	114: 29 ex-, 30 current- and 55 never, M+F, 25-41 yrs	Diff FEV_1 (L) at 2 wks Ex 0.14 (-0.07, 0.31) Current 0.08 (-0.05, 0.32) Never 0.30 (0.18, 0.77) After 2-week ICS treatment, FEV_1 %predicted improved less in current-smokers than never-smokers (2.4% versus 8.1%, P=0.010), and ex-smokers tended to improve less than never-smokers (4.1%, P=0.067).
Budulac (2012) (10)	Netherlands	21 (16 – 22) yrs follow-up	cohort study	Vlagtwedde-Vlaardingen population-based Not reliable, ref to results of an ongoing study with no results available yet	1390: never 445, ex 456, current 489; M+F; age 52 (43-60) yrs	Subjects who quit smoking had (B (regression coefficient) (95%CI)= 20.3 mL (9.49 – 31.15)) significantly less FEV_1 decline per year than subjects who continued smoking. Ex-smokers who restarted smoking had a faster FEV_1 decline (B (95%CI)=214.7 mL (231.5 - 2.1)) per year than ex-smokers who did not restart smoking, although this did not reach significance

(table continues)

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Source	Country	Period	Design	Study population	Study size (n), sex, age (mean±sem or range)	Comments
Tashkin (2011) (25)	Multinational	May 2006-Apr 2009	RCT varenicline vs Pbo; 12 wks trt, 40 wks FU	Mild-moderate COPD smokers	504, M+F, 57.1 yrs	Changes from baseline in FEV_1: LS mean (95%CI) Wk Abstinent Smokers P 12 121.8 (85.0;158.5) 37.9 (14.0;61.9) 0.007 24 58.4 (5.7;11.0) -19.1 (-50.3;12.1) 0.07 52 -9.6(-73.4;54.1) -46.3(-81.3;-11.4) 0.46
Zhou (2010) (8)	China	Sept 02-May 07	Cluster randomized, to intensive program or normal for prevention of COPD	COPD:or healthy Never 239+232; Ex 96+72; Current 94+127	872, M+F, 40-89	FEV_1 decline mean (SEM) Never Ex Current Int 14(4) 38(7) 66(7) Ctr 40(5) 55(8) 63(6) Comparisons between groups
Jang (2010) (24)	Korea	3-months follow-up	Small cohort	Asthmatic smokers and quitters	32: 22 smokers, 10 quitters; M+F, age 53.3±4.3 yrs (Q) and 45.6±2.5 yrs (S)	Quitters showed a greater percent change in FEV_1 (19.1±6.3 vs. 7.9±2.4%, P=0.024) and FEV_1/FVC (6.5±4.14 vs. 3.5±1.5%, P=0.05) than smokers
Kotz (2011) (13)	Netherlands	2,4 yrs follow-up	Cohort	Smokers	255 FU, 47 non-smokers, M+F, 50.0 (8.3) yrs	NS (46) Smoker (201) P FEV_1 -0.080 (0.23) -0.058 (0.21) 0.532 FEV_1%pred -0.211 (6.97) -0.070 (6.45) 0.895 FVC (L) -0.051 (0.33) -0.039 (0.42) 0.859 FEV_1/FVC -1.31 (4.40) -1.18 (4.77) 0.869

(table continues)

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Source	Country	Period	Design	Study population	Study size (n), sex, age (mean±sem or range)	Comments
Tashkin (2010) (9)	37 countries	4 Yrs	UPLIFT - RCT tiotropium vs placebo	COPD smokers	5993; M+F; 65 ± 8yrs	Baseline FEV_1: Smoker 1.2L; IS 1.1L; Ex 1.06L Annual rate of decline CS:-51±4, IS -36±2, Ex -23±2 mL/yr
Kohansal (2009) (6)	US	1971 - 1997	Framingham cohort			Significant variability in the rate of decline of lung function in continuous smokers, both in males (from 8 to 63 mL/yr) and females (from 14 to 49 mL/yr). The mean FEV_1 decline value (and 95% confidence intervals) for each curve of quitters for males was 15.5 mL (11.3–19.8) in quitters before the age of 30, 24.0 mL (20.0–28.1) in quitters between 30 and 40 years of age, and 28.9mL (26.4–31.1) in quitters after the age of 40; for females, 10.4 mL (6.3–14.5) in quitters before the age of 30, 16.5 mL (14.0–19.0) in quitters between 30 and 40 years of age, and 21.0 mL(18.8–23.2) in quitters after the age of 40. *P<0.05 versus healthy never-smokers (NS). #P<0.05 versus CS

(table continues)

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Source	Country	Period	Design	Study population	Study size (n), sex, age (mean±sem or range)	Comments
Clennell (2008) (7)	UK	People born 1st week of March 1946	Cohort study	Population-based	3387 M+F: never smokers 950, predominantly non-smokers 1101, predominantly smokers 715, lifelong smokers 621	Lifelong smokers had a marked decline in lung function between 43 and 53 years (218.0 mL/year, 95%CI 222.3 to 212.8) compared with never smokers, and three times that estimated between predominantly smokers and never smokers (Table 3). No evidence for a difference in the rate of decline was found between predominantly non-smokers and never smokers. From the most recent smoking status available, the lung function of current smokers was found to have declined at a rate of 8.4 mL/year (95%CI 212.0 to 25.0) faster than never smokers. Former smokers recorded no significant difference in rate of decline in lung function relative to those who had never smoked. Similar results were obtained for rates of change in lung function using smoking status at age 25 years

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6 CONCLUSION

The literature search provided no evidence of a strong direct link between FEV_1 and smoking cessation. FEV_1, as a marker of airflow limitation, is valuable in establishing a diagnosis and to assess the severity and progression of a respiratory disease. Whilst some studies showed a short-term improvement in FEV_1 after smoking cessation, it was not consistently the case, probably due to the relatively large variability of this criterion. Because of this variability, FEV_1 is not routinely used as a biomarker for the assessment of cigarette-smoking cessation in the short term, i.e. less than three months duration.

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8 APPENDICES

8.1 Appendix 1 References related to the included studies

8.2 Appendix 2 Excluded studies from search 1

8.3 Appendix 3 Excluded studies from search 2

8.4 Appendix 4 Excluded studies from search 3

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8.2 Appendix 2 Excluded studies from search 1

Literature retrieved using Search 1: To identify literature that linked smoking or nicotine replacement to FEV1 using the search string: (forced expiratory volume OR FEV) AND (smokers OR smoking OR nicotine replacement OR cessation) AND ("2008"[Date - Publication]: "2015"[Date - Publication]) AND English[Language].

E1. FEV1 used only as control/biomarker of exposure

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1733 Niedoszytko M, Grucha?a-Niedoszytko M, Che?minska M, Sieminska A, Jassem E. Persistent impact of cigarette smoking on asthma. J Asthma. 2008 Aug;45(6):495-9. doi: 10.1080/02770900802074810. PubMed PMID: 18612903.

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8.3 Appendix 3 Excluded studies from search 2

Search 2: To identify literature reporting an association between FEV1 and cardiovascular disease using the search string: (forced expiratory volume OR FEV1) AND ((cardiovascular disease) AND (association)) AND ("2008"[Date - Publication]: "2015"[Date - Publication])))) AND English[Language]).

E1. FEV1 used only as control/biomarker of exposure

14 Wannamethee SG, Welsh P, Papacosta O, Lennon L, Whincup PH, Sattar N. Elevated parathyroid hormone, but not vitamin D deficiency, is associated with increased risk of heart failure in older men with and without cardiovascular disease. Circ Heart Fail. 2014 Sep;7(5):732-9. doi: 10.1161/CIRCHEARTFAILURE.114.001272. Epub 2014 Aug 7. PubMed PMID: 25104043.

E2. FEV1 lacked link to disease or smoking

15 Min KB, Min JY. Reduced lung function, C-reactive protein, and increased risk of cardiovascular mortality. Circ J. 2014;78(9):2309-16. Epub 2014 Jun 30. PubMed PMID: 24976509.

51 Lipowicz A, Szklarska A, Malina RM. Allostatic load and socioeconomic status in Polish adult men. J Biosoc Sci. 2014 Mar;46(2):155-67. doi: 10.1017/S0021932013000345. Epub 2013 Jun 28. PubMed PMID: 23806750.

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E3. Disease not covered by search categories

1 Georgiopoulou VV, Deka A, Li S, Niazi AA, Farooq K, Kalogeropoulos AP, Butler J, Alexopoulos D. Pulmonary Function Testing and Outcomes in Subjects With Heart Failure Listed for Heart Transplantation. Respir Care. 2015 Mar 3. pii: respcare.03709. [Epub ahead of print] PubMed PMID: 25737570.

5 Park HY, Jhun BW, Jeong HJ, Chon HR, Koh WJ, Suh GY, Kim H, Chung MJ, Jun HJ, Choi YH, Lim SY. The Complex Association of Metabolic Syndrome and Its Components with Computed Tomography-Determined Emphysema Index. Metab Syndr Relat Disord. 2015 Jan 8. [Epub ahead of print] PubMed PMID: 25569241.

13 Datta S, Pal M, DE A. The dependency of vitamin d status on anthropometric data. Malays J Med Sci. 2014 May;21(3):54-61. PubMed PMID: 25246836; PubMed Central PMCID: PMC4163559.

23 Lee HM, Liu M, Lee K, Luo Y, Wong ND. Does low vitamin D amplify the association of COPD with total and cardiovascular disease mortality? Clin Cardiol. 2014 Aug;37(8):473-8. doi: 10.1002/clc.22284. Epub 2014 Apr 9. PubMed PMID: 24719373.

106 Schäper C, Gläser S, Wolff B, Koch B, Vietzke G, Felix SB, Kleber FX, Opitz CF, Ewert R. Resting alveolar gas tensions as a mortality prognosticator in chronic heart failure. Transplant Proc. 2010 Sep;42(7):2681-6. doi: 10.1016/j.transproceed.2010.05.166. PubMed PMID: 20832569.

111 Koskenvuo JW, Kantola IM, Nuutila P, Knuuti J, Parkkola R, Mononen I, Hurme S, Kalliokoski R, Viikari JS, Wendelin-Saarenhovi M, Kiviniemi TO, Hartiala JJ. Cardiopulmonary involvement in Fabry's disease. Acta Cardiol. 2010 Apr;65(2):185-92. PubMed PMID: 20458826.

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147 Kan H, Stevens J, Heiss G, Rose KM, London SJ. Dietary fiber, lung function, and chronic obstructive pulmonary disease in the atherosclerosis risk in communities study. Am J Epidemiol. 2008 Mar 1;167(5):570-8. Epub 2007 Dec 5. PubMed PMID: 18063592; PubMed Central PMCID: PMC2377022.

E5. Studies in narrow a population (e.g. pregnant women)

12 Steinmann M, Abbas C, Singer F, Casaulta C, Regamey N, Haffner D, Fischer DC, Simonetti GD. Arterial stiffness is increased in asthmatic children. Eur J Pediatr. 2014 Sep 25. [Epub ahead of print] PubMed PMID: 25248341.

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E8. Studies with no comparison to smoking and cessation/switching

8 Lee HM, Liu MA, Barrett-Connor E, Wong ND. Association of lung function with coronary heart disease and cardiovascular disease outcomes in elderly: the Rancho Bernardo study. Respir Med. 2014 Dec;108(12):1779-85. doi: 10.1016/j.rmed.2014.09.016. Epub 2014 Oct 6. PubMed PMID: 25448311; PubMed Central PMCID: PMC4254667.

92 Schnabel E, Karrasch S, Schulz H, Gläser S, Meisinger C, Heier M, Peters A, Wichmann HE, Behr J, Huber RM, Heinrich J; Cooperative Health Research in the Region of Augsburg (KORA) Study Group. High blood pressure, antihypertensive medication and lung function in a general adult population. Respir Res. 2011 Apr 21;12:50. doi: 10.1186/1465-9921-12-50. PubMed PMID: 21510847; PubMed Central PMCID: PMC3090996.

E9. FEV1 not measured or presented as AUC

44 Aykan AÇ, Gökdeniz T, Boyac? F, Gül I, Hatem E, Kalayc?o?lu E, Turan T, Bekta? H, Cilingir MB, Aykan DA, Ayy?ld?z F, Altun S. Assessment of arterial stiffness in chronic obstructive pulmonary disease by a novel method: cardio-ankle vascular index. Herz. 2014 Nov;39(7):822-7. doi: 10.1007/s00059-013-3902-3. Epub 2013 Aug 3. PubMed PMID: 23907692.

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8.4 Appendix 4 Excluded studies from search 3

Search 3: To identify literature reporting an association between FEV1 and respiratory disease using the search string: (forced expiratory volume OR FEV1) AND ((respiratory disease) AND (association)) AND ("2008"[Date - Publication]: "2015"[Date - Publication])) AND English[Language]).

E1. FEV1 used only as control/biomarker of exposure

11 Gompelmann D, Eberhardt R, Herth F. Endoscopic volume reduction in COPD- a critical review. Dtsch Arztebl Int. 2014 Dec 5;111(49):827-33. doi: 10.3238/arztebl.2014.0827. PubMed PMID: 25556601; PubMed Central PMCID: PMC4284519.

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36 Mineshita M, Kida H, Handa H, Nishine H, Furuya N, Nobuyama S, Inoue T, Matsuoka S, Miyazawa T. The correlation between lung sound distribution and pulmonary function in COPD patients. PLoS One. 2014 Sep 22;9(9):e107506. doi: 10.1371/journal.pone.0107506. eCollection 2014. PubMed PMID: 25244247; PubMed Central PMCID: PMC4171498.

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47 Tsai Y, Ko Y, Huang M, Lin M, Wu C, Wang C, Chen Y, Li J, Tseng Y, Wang T. CHI3L1 polymorphisms associate with asthma in a Taiwanese population. BMC Med Genet. 2014 Jul 23;15:86. doi: 10.1186/1471-2350-15-86. PubMed PMID: 25056157; PubMed Central PMCID: PMC4113488.

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49 Lee JS, Bae JS, Park BL, Cheong HS, Kim JH, Kim JY, Namgoong S, Kim JO, Park CS, Shin HD. Association Analysis of TEC Polymorphisms with Aspirin-Exacerbated Respiratory Disease in a Korean Population. Genomics Inform. 2014 Jun;12(2):58-63. doi: 10.5808/GI.2014.12.2.58. Epub 2014 Jun 30. PubMed PMID: 25031568; PubMed Central PMCID: PMC4099349.

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55 Raeiszadeh Jahromi S, Mahesh PA, Jayaraj BS, Madhunapantula SR, Holla AD, Vishweswaraiah S, Ramachandra NB. Serum levels of IL-10, IL-17F and IL-33 in patients with asthma: a case-control study. J Asthma. 2014 Dec;51(10):1004-13. doi: 10.3109/02770903.2014.938353. Epub 2014 Jul 18. PubMed PMID: 24960440.

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