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Summarising published results from spirometric surveys of COPD; the problem of inconsistent definitions

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Abstract

Background—Guidelines specify a definition of chronic obstructive pulmonary disease (COPD) as a post-bronchodilator ratio of one-second forced expiratory volume (FEV1) to forced vital capacity (FVC) of less than70%. Some investigators apply this type of “fixed ratio” criterion while more recently others employ a threshold based on the age-sex specific predicted lower limit of normal (LLN). Further studies still report prevalences based on pre-bronchodilator spirometry. The impact of these different methods on prevalence estimates is poorly understood and makes an informative review of the available prevalence surveys impossible.

Methods—Pre- and post-bronchodilator spirometry results were taken from the Burden of Obstructive Lung Disease (BOLD) survey in 16 centres. Using a post-bronchodilator ratio less than LLN as our gold standard, we calculated simple multiplicative adjustments to calibrate other reported prevalence estimates to gold standard equivalent estimates. These adjustments were then tested on independent data sets from six further BOLD centres and five PLATINO study centres.

Results—Prevalence estimates based on pre-bronchodilator fixed ratio measurements were 5-25% higher than the directly measured value and were strongly positively biased with age and prevalence level. Applying simple multiplicative adjustments gave prevalence estimates that were almost unbiased and within 5% of the directly measured result.

Conclusions—Using the BOLD data we have been able to estimate COPD prevalences based on post-bronchodilator FEV1/FVC<LLN by adjusting estimates based on other common definitions. This makes possible wider and more meaningful comparisons of available published findings.

Introduction

There is good reason to believe that chronic obstructive pulmonary disease (COPD) is a common cause of death and disability world-wide. (1)Nevertheless there is relatively little direct evidence in relation to its prevalence globally. This is in part because the condition is

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defined by spirometry and spirometric surveys of general populations have been uncommon. (2)However, variation in the methods used to assess the prevalence of disease, when such surveys have been undertaken, has also seriously reduced the availability of data on prevalence based on standard definitions.

Measurement of chronic airflow obstruction (CAO) is central to the diagnosis of chronic obstructive pulmonary disease (COPD) where CAO is defined in this context as a low ratio of one-second forced expiratory volume (FEV1) to forced vital capacity (FVC) after inhaling a bronchodilator. However, the definition of "low" varies. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) has provided a definition of COPD as a post-bronchodilator FEV_1/FVC ratio of less than 70%, where bronchodilation using inhalation of 400µg albuterol (salbutamol) is suggested. (3)Because the FEV_1/FVC ratio is strongly dependent on age, an argument has been made for defining COPD as a ratio below the lower limit of normal (LLN) instead. (4) The use of these different criteria, and the practice in many cases of not using a bronchodilator, complicate meaningful comparisons of reported COPD prevalences in the literature.

Conversion of prevalence estimates made using one set of spirometric criteria to those that would be expected if an alternative set of spirometric criteria had been applied by the computation of adjustment factors would allow the comparison of studies that had used different criteria. In this study we have used data from 16 BOLD surveys to estimate the adjustment factors and have corroborated these using data from six more recently completed BOLD surveys, as well as the five PLATINO surveys.

Methods

Datasets

Both the BOLD (5,6) and PLATINO (7) studies are international studies of the burden of COPD which use similar protocols to assess pre- and post-bronchodilator spirometry in populations aged 40 years old and over. The estimation of the adjustment factors are based on results from the first 16 BOLD centres in 15 countries using the same study protocol but covering a range of incomes and health service models (see Table 1). Data from a further six BOLD centres as well as the PLATINO (7) sites, in Latin America, were used to corroborate the results. In all centres bronchodilator spirometry was measured before and between 15 and 60 minutes after 200µg salbutamol administered by a spacer.

Analytic Methods

Given the limited number of centres and the need to derive standard estimates from the published literature, we have computed a simple ratio to adjust other studies' prevalence estimates to a definition based on post-bronchodilator spirometry using the LLN reference values derived from the NHANES survey. (8)

If we have a prevalence based on an alternative definition (P') and we wish to calculate the equivalent prevalence using our "gold standard" definition (P) we first use the BOLD data to derive a conversion ratio P/P'. In any new survey (S) that has estimated the prevalence using

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the alternative definition (P'_S), we then estimate the "gold standard" prevalence in that population (P_S) from:

$$P_s = P'_s * P / P'.$$

This can also be calculated for specific age (i) and sex (j) groups: $P_{Sij} = P'_{Sij} * P_{ij} / P'_{ij}$.

We have estimated the conversion ratios using the BOLD data from two of the most commonly found alternative estimates in the literature, the prevalence of a pre-bronchodilator FEV_1/FVC of less than 70% and also to a post-bronchodilator FEV_1/FVC of less than 70% and converted these to the "gold standard" used in BOLD of a post-bronchodilator FEV_1/FVC less than the lower limit of normal (conversion ratios for further outcomes are available in the web annex).

To validate the performance of these ratios in independent datasets, this comparison was repeated using the ratios calculated using the initial 16 centres in two further available datasets: six more recently completed BOLD surveys and five Latin American centres from the PLATINO study. (7) To provide a conservative estimate of performance we used a sex-specific, all-ages (40+ years) ratio. We have plotted the differences in derived estimates from the directly measured estimates of the prevalence of a FEV1/FVC < LLN in a Bland-Altman plot. (9)

Results

Table 1 gives the estimated prevalence of CAO using three different definitions (post-bronchodilator FEV_1/FVC<LLN ("gold standard"), post-bronchodilator FEV_1/FVC<70% and pre-bronchodilator FEV_1/FVC<70%). Compared with the ratio < LLN definition the GOLD definition (post-bronchodilator ratio < 70%) gives higher prevalences and the pre-bronchodilator ratio < 70% definition higher prevalences still.

Table 2 gives the age-sex specific and sex-specific conversion ratios for participants over the age of 40 years derived from the initial 16 BOLD sites. Compared to the reference definition, the use of a fixed ratio generally increases the estimated prevalence of CAO, more so in older participants, whilst not using a bronchodilator tends to increase the estimated prevalence of disease even more.

The estimates of obstruction given by a pre-bronchodilator FEV_1/FVC < 70% fixed cut off point and the adjusted estimate (derived by applying the conversion ratios to the same data) were each compared with the reference estimate based on a post-bronchodilator FEV_1/FVC <LLN. Figure 1 shows this as a Bland-Altman plot with the differences between these estimates and the "gold standard" on the y-axis and the means of these estimates and the "gold standard" on the x-axis. The unadjusted pre-bronchodilator ratio <70% (open squares (men) and open circles (women)) is a poor estimate of the post-bronchodilator ratio < lower limit of normal, giving values that increase with prevalence (that is, show bias) and are consistently between 5% and 25% points higher than the directly measured reference value. The adjusted values, estimated using the conversion factor (closed squares (men); closed

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circles (women)) are by definition, on average, the same as the true values, but appear independent of prevalence rate and are almost all confined between +/− 5% points of the measured values.

To verify that the ratios derived from BOLD were effective in independent datasets this comparison was repeated on two further available datasets: six later BOLD surveys and five Latin American centres in PLATINO, an international study using a similar protocol to BOLD. Table 3 gives the directly measured prevalence of COPD in these eleven test sites using the same definitions as before. A similar pattern is seen again in which the post-bronchodilator ratio<70% gives rise to higher prevalences than seen with our "gold standard" definition and the pre-bronchodilator ratio<70% gives higher prevalences still. Figure 2 is the Bland-Altman plot comparing the post-bronchodilator ratio < LLN with the pre-bronchodilator ratio < 70% cut-off before and after adjustment using the conversion ratios derived from the analysis of the initial 16 BOLD sites and compared with the "gold standard" of directly measured post-bronchodilator ratio < LLN. The unadjusted values are all between 4 and 23% higher than the directly measured result, whereas the adjusted results all fall within 5% of the directly observed result and are more evenly distributed around it.

Discussion

The wide variety of outcome measures currently used to estimate the prevalence of COPD in published studies makes comparisons across global regions and over time uninformative (when using different definitions) or limited (when using only one). Using the largest international study of COPD prevalence, we have derived conversion ratios which enable such comparisons to be made using the prevalence of post-bronchodilator FEV_1/FVC<LLN as the reference method. The resulting adjusted prevalence estimates, when applied to both BOLD and other independent study samples, do not vary systematically by prevalence and in each case provide prevalence estimates very much closer to the outcome of choice. The conversion ratios are presented here for four decennial age categories in the over 40s as well as for all-ages over 40 years. The accuracy of the adjusted estimates in men and women of all-ages over 40 years are also illustrated as a conservative estimate of the efficacy of the ratio, but tests were made in age-sex specific samples and show similar results.

There is good agreement that COPD should be defined by the ratio of post-bronchodilator FEV_1/ FVC, but less agreement on what criterion should be used. The GOLD guidelines recommend that the fixed cut off of 70% should be used at all age groups. This has the advantage of simplicity, though this seems a minor consideration now that all spirometers include powerful microchips and can easily report the lower limits of normal.

The disadvantage in using the fixed cut-off is that ventilatory function declines with age. Even those few who argue that this decline, though universal, should still be treated as pathological, generally adjust their analyses for age. This is possible when analysing individual data, but not when analysing grouped data (such as prevalence). Here the great diversity in the age structures of populations makes any prevalence based on the fixed ratio very difficult to interpret.

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The usual solution to this problem is to select only "GOLD stage II" disease. (10) This is defined as a FEV_1/FVC ratio < 70% and a FEV_1 < 80% of the predicted FEV_1 for age, sex and height. This has the effect of at least partially adjusting the measurement for age. However it makes the initial problem even worse. First, because the distribution of the predicted value of FEV_1 decreases with age, the 80% deficit in predicted FEV_1 also slightly underestimates the lower limit of normal. Second, because the FEV_1 is influenced not just by the obstruction of the airway but also by the size of the lungs, its use confuses restriction, which also increases with age, with obstruction. GOLD Stage II is a hybrid measure of both low FVC and low FEV_1/FVC ratio.(11)

BOLD and PLATINO use a 200 μg dose of salbutamol administered via a spacer to assess post-bronchodilator ventilatory function, which is lower than the 400mg dose recommended by GOLD. As these are surveys in normal subjects not used to taking inhaled β-agonists it was felt that the side-effects that are common at 400μg would not be acceptable and it was noted that the effective maximum bronchodilation in normal subjects occurs somewhere between 100 and 300 μgs.(12)

The GOLD guidelines have been successful in reducing the variability of reporting but there is still a very wide variation in practice. In a recent unpublished review we found 10 different variations of indices used to diagnose COPD based on the FEV_1/FVC ratio including

FEV_1/FVC<60%, FEV_1/FVC<80%, FEV_1/FVC<88 % predicted for men; < 89% predicted for women and 70%≤FEV_1/FVC<80%, with yet more definitions not based on the FEV_1/FVC ratio. It would be useful to see this harmonisation increase, but even better if the standard moved away from the fixed cut off. In the meantime there will be a need for methods to standardise the very different estimates from the published sources. This paper goes some way to filling this gap.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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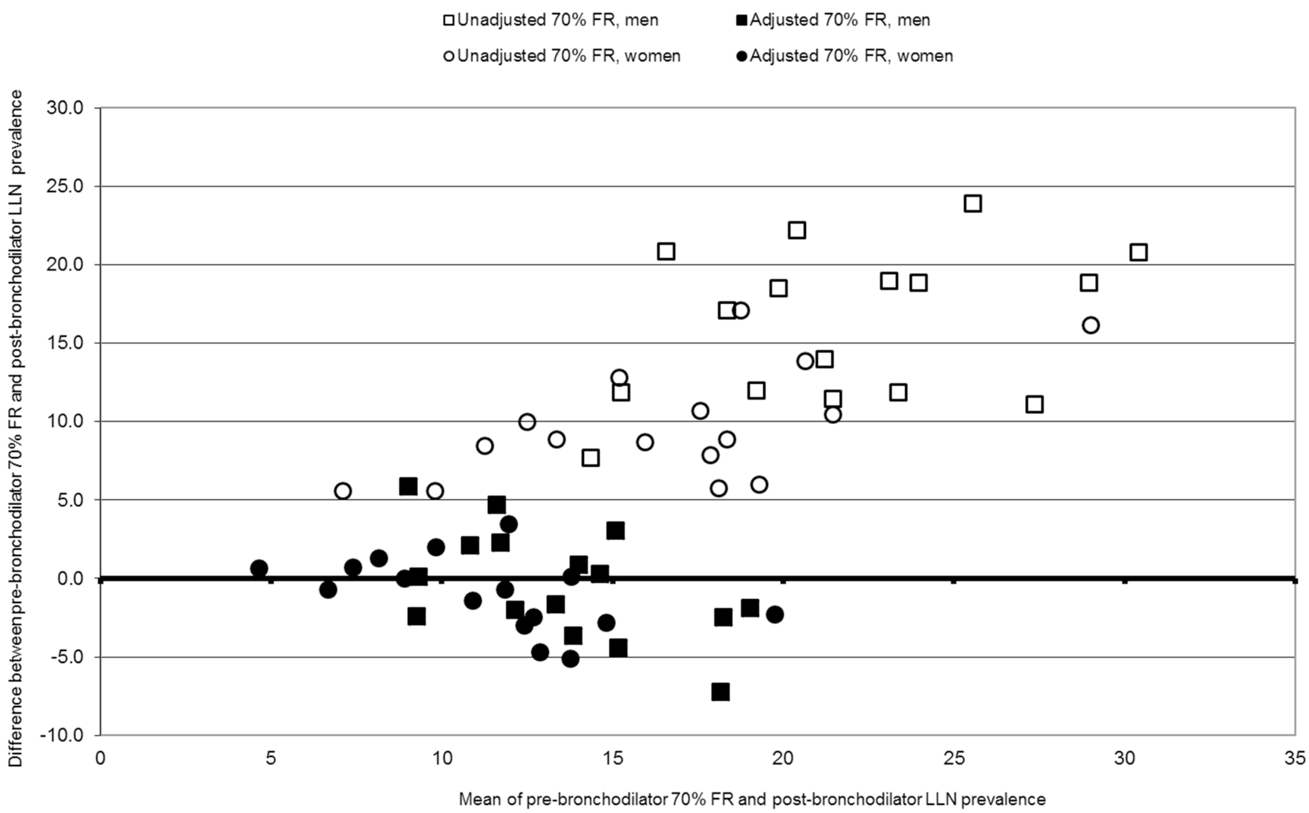

Figure 1.

Bland-Altman plot comparing unadjusted and adjusted pre-bronchodilator 70% fixed ratio prevalence estimates with post-bronchodilator LLN prevalence in men and women, in the initial 16 BOLD centres.

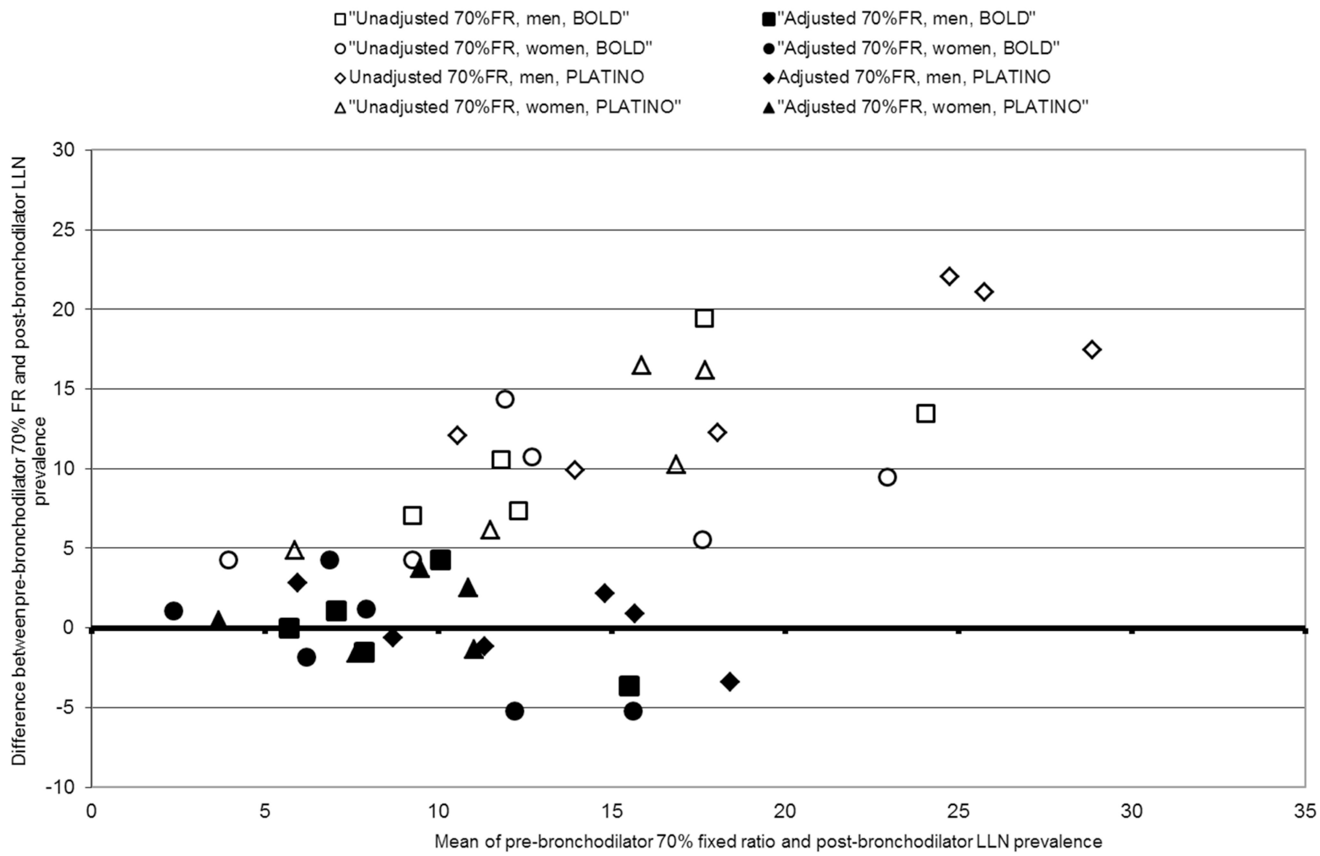

Figure 2.

Bland-Altman plot comparing unadjusted and adjusted pre-bronchodilator 70% fixed ratio prevalence estimates with post-bronchodilator LLN prevalence in men and women, PLATINO and further 6 BOLD centres.

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Table 1

Directly observed prevalence of COA in 16 BOLD sites using different definitions of COPD.

BOLD site	Post-bronchodilator FEV1/FVC<LLN		Post-bronchodilator FEV1/FVC<70%		Pre-bronchodilator FEV1/FVC<70%	
	Male	Female	Male	Female	Male	Female
Sydney, Australia	6.1 (1.6)	13.9 (2.2)	18.5 (2.5)	19.6 (2.6)	27.0 (2.9)	22.8 (2.7)
Reykyavik, Iceland	9.3 (1.5)	13.7 (1.9)	18.2 (2.0)	17.4 (2.1)	31.5 (2.3)	27.6 (2.5)
Lisbon, Portugal	9.3 (2.4)	7.5 (1.2)	18.7 (3.4)	10.7 (1.6)	21.2 (3.8)	17.5 (1.3)
Hannover, Germany	9.8 (1.7)	7.0 (1.5)	18.3 (2.3)	9.6 (1.7)	26.9 (2.6)	15.5 (2.2)
Guangzhou, China	10.5 (2.1)	7.0 (1.9)	15.3 (2.5)	8.5 (2.0)	18.2 (2.6)	12.6 (2.4)
Uppsala, Sweden	10.6 (1.9)	8.8 (1.9)	19.1 (2.5)	14.7 (2.4)	29.1 (2.8)	21.6 (2.8)
Lexington, USA	13.2 (2.5)	15.2 (2.5)	19.6 (3.0)	19.3 (2.8)	25.2 (3.3)	21 (2.9)
Krakow, Poland	13.6 (2.1)	11.6 (2.0)	27.0 (2.5)	16.2 (2.3)	32.6 (2.8)	20.3 (2.6)
Salzburg, Austria	13.6 (1.4)	20.9 (1.9)	27.2 (1.8)	26.0 (2.1)	37.5 (2.0)	37.1 (2.3)
Vancouver, Canada	14.2 (2.0)	12.2 (1.6)	21.3 (2.4)	16.3 (1.8)	28.2 (2.6)	22.9 (2.0)
Bergen, Norway	14.5 (2.0)	10.2 (1.8)	23.2 (2.4)	15.3 (2.0)	33.4 (2.7)	27.3 (2.6)
Phililppines, urban	15.7 (2.5)	4.3 (0.8)	20.5 (2.0)	8.2 (1.1)	27.2 (2.2)	9.9 (1.6)
Phililppines, rural	17.4 (1.9)	13.9 (2.4)	26.5 (2.7)	15.4 (2.5)	29.3 (2.1)	21.8 (2.1)
London, UK	19.6 (3.2)	16.2 (2.9)	29.5 (3.5)	19.3 (3.1)	38.4 (3.5)	26.7 (3.4)
Adana, Turkey	20.0 (2.1)	8.9 (1.8)	28.8 (2.0)	10.4 (2.0)	40.8 (2.5)	17.8 (2.4)
Cape Town, S.Africa	21.8 (2.5)	16.3 (1.8)	27.3 (2.7)	19.6 (2.0)	32.9 (2.9)	22.3 (22.3)

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Table 2

Age-sex specific and sex-specific conversion ratios to estimate the prevalence of reference Chronic Obstructive Airways (COA) disease (post-bronchodilator FEV1/FVC < Lower Limit of Normal) from two commonly presented COA prevalence estimates.

	Post-bronchodilator FEV1/FVC<LLN		**Post-bronchodilator FEV1/FVC<70%**		**Pre-bronchodilator FEV1/FVC<70%**	
Age group	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**
40-49 years	1	1	0.83	1.57	0.54	0.87
50-59 years	1	1	0.71	0.88	0.57	0.54
60-69 years	1	1	0.45	0.71	0.35	0.39
70+ years	1	1	0.50	0.54	0.36	0.34
40+ years	1	1	0.59	0.80	0.44	0.47

Note.

For example, to obtain the reference prevalence(post-bronchodilator FEV1/FVC<LLN) in males aged 50-59 given the prevalence in that age-sex group of COA using the definition of pre-bronchodilator FEV1/FVC<70%, multiply the given prevalence by 0.57.

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Table 3

Directly observed prevalence of COA in 5 PLATINO and 6 more recent BOLD sites using different definitions of COA.

Test site	Post-bronchodilator FEV1/FVC<LLN		Post-bronchodilator FEV1/FVC<70%		Pre-bronchodilator FEV1/FVC<70%	
	Male	Female	Male	Female	Male	Female
Mexico City, Mexico (P)	4.5 (0.9)	3.4 (0.8)	11.1 (1.7)	5.3 (1.0)	16.6 (2.0)	8.3 (1.2)
Caracas, Venezuela (P)	9.0 (1.6)	8.4 (1.1)	15.6 (1.6)	9.9 (1.0)	18.9 (1.7)	14.6 (1.1)
Sao Paulo, Brazil (P)	11.9 (1.5)	11.7 (1.4)	17.5 (1.7)	14.2 (1.5)	24.2 (1.9)	22.0 (2.1)
Santiago, Chile (P)	13.7 (1.4)	7.6 (1.1)	23.2 (1.8)	11.8 (1.3)	35.8 (2.3)	24.1 (1.7)
Montevideo, Uruguay (P)	15.2 (1.9)	9.6 (1.3)	26.9 (2.2)	14.5 (1.5)	36.3 (2.3)	25.8 (1.8)
Maastricht, Netherlands (B)	20.1 (2.5)	18.2 (2.9)	29.1 (2.9)	20.0 (3.1)	37.6 (3.0)	27.8 (3.2)
Mumbai, India (B)	5.7 (1.4)	7.3 (2.3)	9.4 (1.8)	7.1 (2.4)	12.8 (2.1)	18.1 (5.2)
Pune, India (B)	6.5 (1.2)	7.1 (1.6)	11.2 (1.5)	7.1 (1.6)	17.1 (1.8)	11.4 (1.9)
Sousse, Tunisia (B)	8.6 (2.1)	1.8 (0.7)	13.6 (2.7)	1.9 (0.7)	16.0 (2.9)	6.1 (1.3)
Srinagar, India (B)	17.4 (3.9)	14.8 (2.2)	23.4 (4.7)	14.8 (2.1)	30.8 (5.6)	20.4 (3.2)
Tartu, Estonia (B)	7.9 (1.5)	4.7 (1.2)	16.5 (2.1)	10.4 (1.8)	27.4 (2.6)	19.1 (2.3)