Unidirectional Expiratory Valve Method to Assess Maximal Inspiratory Pressure in Individuals without Artificial Airway

Samantha Torres Grams¹, Karen Yumi Mota Kimoto¹, Elen Moda de Oliveira Azevedo¹, Marina Lança¹, André Luís Pereira de Albuquerque¹,², Christina May Moran de Brito¹, Wellington Pereira Yamaguti¹*¹

¹ Department of Rehabilitation, Hospital Sírio-Libanês (HSL), São Paulo, São Paulo, Brazil, ² Department of Pulmonary Function–Núcleo Avançado de Tórax (NAT), Hospital Sírio-Libanês (HSL), São Paulo, São Paulo, Brazil

* wellington.psyamaguti@hsl.org.br

Abstract

Introduction
Maximal Inspiratory Pressure (MIP) is considered an effective method to estimate strength of inspiratory muscles, but still leads to false positive diagnosis. Although MIP assessment with unidirectional expiratory valve method has been used in patients undergoing mechanical ventilation, no previous studies investigated the application of this method in subjects without artificial airway.

Objectives
This study aimed to compare the MIP values assessed by standard method (MIPsta) and by unidirectional expiratory valve method (MIPuni) in subjects with spontaneous breathing without artificial airway. MIPuni reproducibility was also evaluated.

Methods
This was a crossover design study, and 31 subjects performed MIPsta and MIPuni in a random order. MIPsta measured MIP maintaining negative pressure for at least one second after forceful expiration. MIPuni measured MIP using a unidirectional expiratory valve attached to a face mask and was conducted by two evaluators (A and B) at two moments (Tests 1 and 2) to determine interobserver and intraobserver reproducibility of MIP values. Intraclass correlation coefficient (ICC[2,1]) was used to determine intraobserver and interobserver reproducibility.

Results
The mean values for MIPuni were 14.3% higher (-117.3 ± 24.8 cmH₂O) than the mean values for MIPsta (-102.5 ± 23.9 cmH₂O) (p<0.001). Interobserver reproducibility assessment showed very high correlation for Test 1 (ICC[2,1] = 0.91), and high correlation for Test 2.
(ICC_{2,1} = 0.88). The assessment of the intraobserver reproducibility showed high correlation for evaluator A (ICC_{2,1} = 0.86) and evaluator B (ICC_{2,1} = 0.77).

**Conclusions**
MIP\textsubscript{uni} presented higher values when compared with MIP\textsubscript{sta} and proved to be reproducible in subjects with spontaneous breathing without artificial airway.

**Introduction**
Maximal Inspiratory Pressure (MIP) is considered an effective method to estimate strength of inspiratory muscles [1,2]. This method has been widely used to evaluate the severity and follow-up of inspiratory muscle weakness in several clinical conditions [2–5], as well as for training load prescription and monitoring the outcomes of inspiratory muscle training programs [6–8]. In Intensive Care Units (ICU), MIP has also been used as a predictive index for successful weaning from mechanical ventilation [9,10] and, more recently, as a parameter for early detection of muscle weakness acquired in ICU [11].

The MIP evaluated by standard method (MIP\textsubscript{sta}) proposed by Black and Hyatt [1] is still the most common method for assessment of maximal respiratory pressures. In this method, MIP is quantified by maintaining the negative pressure for at least one second, against an occluded airway, after a forceful expiration near residual volume. Although this method has been considered well tolerated by patients and easy to perform, the measurement depends on the understanding and cooperation of individuals to perform really maximal respiratory efforts [2,12]. Low values (false positive diagnosis) are not uncommon and may represent poor technique of inspiratory effort instead of muscle weakness [13]. Furthermore, methodological variations such as number of necessary maneuvers, lung volume from which the maneuvers have been made, and types of equipment or interface may also compromise the reliability of measures [2,12], creating a discrepancy between the reference values [14–16].

To overcome the need for collaboration during MIP\textsubscript{sta}, Marini et al. [17] developed a method which shows optimization of inspiratory effort in critically ill and poorly cooperative patients undergoing mechanical ventilation. These authors proposed the use of a unidirectional expiratory valve, using low resistance to allow expiration in a selective way, while inspiration was prevented–MIP evaluated by unidirectional expiratory valve method (MIP\textsubscript{uni}). With inspiration blocked, respiratory efforts deflate the chest, making the patients start successive inspiratory efforts increasingly closer to residual volume, stimulating the generation of negative pressure. This method involves less patient-evaluator coordination because it represents a physiological response (increase of the respiratory drive after a prior insufficient inspiration), and can be used in patients unable to collaborate to perform the maneuver by MIP\textsubscript{sta} [18].

Some authors [19,20] compared MIP\textsubscript{sta} and MIP\textsubscript{uni} in mechanically ventilated patients, and observed that MIP\textsubscript{uni} was significantly higher when compared to MIP\textsubscript{sta}, demonstrating that MIP\textsubscript{uni} optimizes inspiratory muscle capacity of action. However, to our knowledge, no study has reported using MIP\textsubscript{uni} in subjects under spontaneous breathing without artificial airway. We hypothesized that the superiority of this method in the optimization of maximal inspiratory effort may also occur in these conditions, with a high reproducibility and better repeatability compared with MIP\textsubscript{sta}. In this context, this study aimed to compare MIP\textsubscript{sta} and MIP\textsubscript{uni} in subjects under spontaneous breathing without artificial airway. MIP\textsubscript{uni} reproducibility and repeatability were also evaluated.
Methods

Subjects

We studied 31 subjects who met the inclusion criteria as follows: (1) age 18–60 years; (2) normal pulmonary function tests (FVC and FEV$_1$ ≥ 80% of predicted and FEV$_1$/FVC ≥ 0.7); (3) non-smokers; (4) absence of cardiopulmonary diseases; and (5) no prior contact with the methods tested. Exclusion criteria were: inability to carry out evaluations within the criteria for technical acceptability. The study was approved by the Sírio-Libanês Hospital Ethics Committee (HSL2011/17), and all subjects provided written informed consent.

Set-up and measurements

Prior to MIP measurements, the subjects underwent assessment of personal history and lifestyle habits through a standard questionnaire, anthropometric evaluation, and pulmonary function test. The level of discomfort during the measurements in both MIP methods was also evaluated.

**Pulmonary function test.** The spirometry was performed using a portable digital spirometer (model Koko PfTesting; nSpire Healthy; Longmont; Colorado; USA), previously calibrated according to ATS and ERS recommendations [21]. The spirometric parameters were presented as absolute values and as a percentage of the predicted [22].

**Maximal inspiratory pressure.** MIP values were obtained with a digital vacuum manometer (model MVD500; Microhard; Porto Alegre; RS; Brazil). MIP$_{sta}$ followed the Brazilian Society of Pulmonology and Phthisiology guidelines [12], using a digital vacuum manometer attached to a mouthpiece with a 2-mm diameter air-leak opening. MIP$_{sta}$ was measured from the volume closest to residual volume by instructing the individuals to realize a forceful expiration followed by a maximal inspiration. For this evaluation, 10 maneuvers [23,24] were realized, respecting a rest period of one minute between them, in order to obtain three acceptable maneuvers including at least two repeatable ones. The highest value among the repeatable maneuvers was considered for the study.

MIP$_{uni}$ was performed by using the digital vacuum manometer attached to a unidirectional expiratory valve and a face mask (Fig 1). The subjects were seated on a comfortable chair and remained attached to the mask for 20 seconds. During this period, all individuals were encouraged to make maximal respiratory efforts. For this evaluation, three maneuvers [19,20] were performed, respecting a rest period of one minute between them, and the highest value among the maneuvers was considered for the study.

**Experimental protocol.** This study used a crossover design. MIP measurements were obtained by MIP$_{sta}$ and MIP$_{uni}$ in all subjects, in a random order of application previously defined through a raffle. A 20-minute rest period was allowed between each method. MIP$_{sta}$ was performed in a single moment (Test 1), and conducted by a single evaluator (evaluator A), who was kept blind to the results. In order to analyze the inter- and intraobserver reproducibility of MIP$_{uni}$ this method was carried out by two evaluators (A and B), independently and in a random order, at two moments (Tests 1 and 2), at least one week apart (Fig 2). Repeatability was determined for each method (MIP$_{sta}$ and MIP$_{uni}$) considering the first and the last measurements from each participant obtained by evaluator A. The technical acceptability and recording of the values obtained in MIP maneuvers were performed by a third evaluator, so that evaluators A and B were kept blind to the results. The same conditions were maintained to perform MIP$_{uni}$ both in Test 1 and Test 2: time of day, position, orientations and randomized order of the evaluators.

The discomfort caused during MIP assessment in both methods was measured by a visual analogue scale [25] of 10 cm, in which the "zero" point corresponded to "no discomfort", and...
point "ten" matched "maximum discomfort." The subjects were asked to mark a point on the scale, quantifying this subjective measure.

Statistical analysis

Data were analyzed using SPSS for Windows, version 17.0 (IMB SPSS Statistics; IBM; Armonk; New York; USA). A sample size of 29 subjects was calculated using the results from a previous study [19] to detect a difference in MIP\textsubscript{uni} of up to 14.06 with a standard deviation of 18.69 compared with MIP\textsubscript{sta} (alpha value of 0.05 and a power of 0.8). Shapiro-Wilk test was used to analyze data distribution. The mean values of MIP\textsubscript{sta} and MIP\textsubscript{uni} were compared using the paired Student’s t-test. This test was also used for comparing the mean values of MIP\textsubscript{uni} for both evaluators (A and B), in both assessments (Tests 1 and 2). The inter- and intraobserver reproducibility of MIP\textsubscript{uni} was established by the intraclass correlation coefficient (ICC\textsubscript{2,1}).

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Fig 1. Materials used for MIP assessment by unidirectional expiratory valve method: (1) unidirectional expiratory valve; (2) straight connector; (3) T-tube; (4) face mask; (5) digital vacuum manometer.

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Fig 2. Process of MIP\textsubscript{uni} assessment.

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two-way random effects model with absolute agreement). The classification system by Munro [26] was used to interpret the ICC[2,1]: 0.0 to 0.25—little if any; 0.26 to 0.49—low; 0.50 to 0.69—moderate; 0.70 to 0.89—high; 0.90 to 1.00—very high. Interobserver and intraobserver reproducibility was also evaluated by Bland-Altman plots [27] in order to better visualize the measurement agreement. To analyze repeatability of the values in both MIPsta and MIPuni, the first and the last measurements of each participant were considered to calculate ICC[2,1] in the first assessment (Test 1). The Bland-Altman repeatability coefficient [27] was also calculated for MIPsta and MIPuni values. The discomfort caused by both MIPuni and MIPsta was compared by using the Wilcoxon test. The significance level was established at 5%.

**Results**

Thirty-one subjects were assessed for eligibility: 17 female and 14 male, with a mean age of 30.8 ± 6.2 years. Anthropometric characteristics and pulmonary function are shown in Table 1.

**MIPsta x MIPuni**

MIPsta (-102.5 ± 23.9 cmH2O) presented a statistically significant difference when compared to MIPuni (-117.3 ± 24.8 cmH2O; p<0.001). MIPuni was 14.9 ± 19.6 cmH2O above MIPsta in absolute values (percentage difference mean of 16.9 ± 24.4%). By means of the Bland-Altman plots, a low agreement between MIPsta and MIPuni absolute values was observed, since the mean difference between obtained values was not close to zero. The dispersion of differences between values was also shown by Bland-Altman plots, with limits of agreement of -23.6 and +53.3 cmH2O (Fig 3). However, a significant positive linear correlation between the methods was observed: MIPuni = (0.701 x MIPsta) + 45.53 (r = 0.68; p<0.001).

**Inter- and intraobserver reproducibility**

MIPuni values obtained by evaluators A and B in both tests are shown in Table 2. No statistically significant difference was found when comparing MIPuni assessed by evaluators A and B, both in Test 1 (p = 0.19) and in Test 2 (p = 0.15). Also, no statistically significant difference

| Variables | Mean ± Standard deviation (n = 31) |
|-----------|-----------------------------------|
| Age (years) | 30.8 ± 6.2 |
| Body mass (kg) | 71.8 ± 13.8 |
| Height (m) | 1.70 ± 0.08 |
| BMI (kg/m²) | 24.5 ± 3.5 |
| Pulmonary function | |
| FVC (% predicted) | 92.4 ± 12.1 |
| FEV₁ (% predicted) | 93.3 ± 10.6 |
| FEV₁/FVC (% predicted) | 101.0 ± 7.2 |
| FEF 25–75% (% predicted) | 95.1 ± 21.1 |
| VC (% predicted) | 90.1 ± 11.1 |
| IC (L) | 2.95 ± 0.63 |
| ERV (L) | 1.02 ± 0.45 |

Table 1. Anthropometric characteristics and pulmonary function variables. n: number of subjects; kg: kilograms; m: meters; BMI: body mass index. FVC (% predicted): estimated percentage of predicted forced vital capacity; FEV₁ (% predicted): estimated percentage of predicted forced expiratory volume in the first second; FEF 25–75% (% predicted): estimated percentage of predicted mean forced expiratory flow between 25% and 75% of FVC; VC (% predicted): estimated percentage of predicted vital capacity; IC: inspiratory capacity (L: liter); ERV: expiratory reserve volume.

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was found when comparing MIPuni assessed by evaluator A, in Tests 1 and 2 (p = 0.10), and when comparing MIPuni assessed by evaluator B, in Tests 1 and 2 (p = 0.13).

In the interobserver reproducibility evaluation, ICC [2,1] was very high between MIPuni obtained by evaluators A and B, in Test 1 (ICC [2,1] = 0.91). In Test 2, ICC [2,1] was high between the values obtained by these evaluators (ICC [2,1] = 0.88). In the intraobserver reproducibility evaluation, ICC [2,1] was high for both MIPuni obtained by evaluator A (ICC [2,1] = 0.86) and that obtained by evaluator B (ICC [2,1] = 0.77) (Table 3).

The Bland-Altman plots showed the agreement between MIPuni values obtained by evaluators A and B in both assessments (interobserver agreement), and also showed measurement agreement between MIP values obtained by each evaluator at two moments – Tests 1 and 2 (intraobserver agreement) (Fig 4).

Repeatability of MIPsta and MIPuni

MIPsta repeatability assessment showed moderate ICC [2,1] (ICC [2,1] = 0.60). On the other hand, MIPuni repeatability assessment showed very high ICC [2,1] both by evaluator A (ICC [2,1] = 0.94) and by evaluator B (ICC [2,1] = 0.91) (Table 4).

The Bland-Altman repeatability coefficient was 49.6 cmH2O for MIPsta. In MIPuni, the Bland-Altman repeatability coefficient obtained by evaluator A was 17.1 cmH2O and by evaluator B it was 21.8 cmH2O (Fig 5).

The discomfort reported during MIPuni was higher (5.7 ± 2.8 cm) compared to MIPsta (1.3 ± 1.6 cm; p < 0.001).

Table 2. MIP evaluated by unidirectional expiratory valve method. n: number of subjects; cmH2O: centimeters of water.

|        | MIPMean ± Standard deviation |
|--------|-------------------------------|
| Test 1 |                               |
| (n = 31)| Evaluator A                  |
|        | -117.3 ± 24.8                 |
| Test 2 |                               |
| (n = 31)| Evaluator A                  |
|        | -113.5 ± 25.0                 |
|        | Evaluator B                  |
|        | -110.2 ± 26.6                 |

Fig 3. Bland-Altman plots of the agreement between MIPsta and MIPuni values (absolute values). MIPsta: Maximal inspiratory pressure evaluated by standard method; MIPuni: Maximal inspiratory pressure evaluated by unidirectional expiratory valve method; X axis: Mean of MIP values obtained by MIPuni and MIPsta for each subject of the study (MIPuni value + MIPsta value /2); Y axis: Difference between MIP values obtained by MIPuni and MIPsta for each subject (MIPuni value – MIPsta value); UL: Upper limit; LL: Lower limit.

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Table 2. MIP evaluated by unidirectional expiratory valve method. n: number of subjects; cmH2O: centimeters of water.
The present study aimed to compare MIP_{sta} and MIP_{uni} in subjects under spontaneous breathing without artificial airway. The results showed significantly higher values of MIP_{uni} when compared to MIP_{sta} values in this population. Furthermore, MIP_{uni} proved to be an inter- and intraobserver reproducible method.

Previous studies [19,20] have also demonstrated superiority of MIP_{uni} when compared to MIP_{sta} but in patients with artificial airway. Possible explanations for the higher MIP values

| ICC[2,1] | CI 95% | p       |
|----------|--------|---------|
| Interobserver reproducibility | Test 1 | 0.91 | 0.83–0.96 | <0.001 |
| | Test 2 | 0.88 | 0.77–0.94 | <0.001 |
| Intraobserver reproducibility | Evaluator A | 0.86 | 0.74–0.93 | <0.001 |
| | Evaluator B | 0.77 | 0.57–0.88 | <0.001 |

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Discussion

The present study aimed to compare MIP_{sta} and MIP_{uni} in subjects under spontaneous breathing without artificial airway. The results showed significantly higher values of MIP_{uni} when compared to MIP_{sta} values in this population. Furthermore, MIP_{uni} proved to be an inter- and intraobserver reproducible method.

Previous studies [19,20] have also demonstrated superiority of MIP_{uni} when compared to MIP_{sta} but in patients with artificial airway. Possible explanations for the higher MIP values
obtained by MIPuni were mentioned by Caruso et al [19]. According to the authors, the respiratory drive increase during maneuvers might be due to the blockage of inspiration by using a unidirectional expiratory valve, which would cause carbon dioxide retention and subsequent release of chemical stimuli after the previous ineffective inspiration. In MIPsta, however, the respiratory drive would depend more on the collaboration of subjects than on physiologic response. Another plausible explanation is that, with the use of a unidirectional expiratory valve and the 20-second blockage of inspiration, patients could be forced to progressively reduce pulmonary volumes, performing inspiratory effort at a pulmonary volume closer to residual volume, optimizing the inspiratory muscle capacity of action (force–length relationship). It is important to mention that, both in MIPsta and MIPuni, the negative pressure generated when the inspiratory effort is realized from the volume closest to residual volume reflects not only the pressure developed by the respiratory muscles, but also the passive elastic recoil pressure of the respiratory system including the lung and chest wall. According to the ATS [2], subjects find it easier to maximize their inspiratory efforts at low lung volumes; therefore, by convention and to standardize measurement, MIP is measured at or close to residual volume.

In the present study, it is worth noting that, for MIPsta evaluation, a mouthpiece was used as interface, while in MIPuni a face-mask was used. The superiority of MIPuni cannot be attributed to the type of interface used, since previous studies have shown no significant difference between MIP values obtained when using a mouthpiece or a face-mask [28,29].

With respect to the differences observed between MIPsta and MIPuni, previous findings have shown that MIPuni presented a variation of approximately 27–30% above MIPsta [19,20]. In our study, the difference between the methods was 14.3%. This lower variation can be due to the differences in the population. The subjects of the present study were younger, healthy and without artificial airway. Older and hospitalized individuals, with artificial airway, such as those included in previous studies, could present less cooperation and worse performance during MIPsta maneuvers.

We also aimed to assess the inter- and intraobserver reproducibility of MIPuni, showing that the method is reproducible. To determine the interobserver reproducibility of MIPuni, ICC[2,1] showed high correlation between values obtained by different evaluators, when the same conditions were maintained during the assessment. Good agreement between values was observed using Bland-Altman plots, since the mean difference between values obtained by the evaluators was close to zero. Concerning the limits of agreement in the Bland-Altman plots, 95% of the difference between values obtained by both evaluators was less than 27.5 cmH2O. The study also assessed the intraobserver reproducibility and showed high ICC[2,1] between values obtained by the same evaluator, at two moments, maintaining similar conditions. The dispersion of differences between values was also shown by Bland-Altman plots, with limits of agreement lower than 37 cmH2O. The same conditions were attempted in the present study for both Tests 1 and 2. Intraindividual variation factors, however, such as motivation during the test day, may have interfered with the results.

The repeatability of the values obtained by MIPsta and MIPuni was also compared. The repeatability analysis allows us to verify if the repeated measurements obtained by a single

| Repeatability | ICC[2,1] | CI 95%  | p  |
|---------------|----------|---------|----|
| MIPsta        | 0.60     | 0.32–0.79 | <0.001 |
| MIPuni—Evaluator A | 0.94 | 0.88–0.97 | <0.001 |
| MIPuni—Evaluator B | 0.91 | 0.83–0.96 | <0.001 |

Table 4. MIP measurement repeatability. ICC[2,1]: intraclass correlation coefficient; CI 95%: 95% confidence interval, p: level of significance.

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evaluator varied, when assessing the same subject with the same instrument, preserving identical conditions during a short period of time [26]. The ICC\[2,1\] showed very high correlation between MIPuni values while it showed moderate correlation between MIPsta measurements. The repeatability coefficient for MIPsta was 49.6 cmH2O, which means that 95% of the

Fig 5. Bland-Altman plots of the agreement between MIP values obtained by standard method and by unidirectional expiratory valve method (absolute values). X axis: Mean between the first and last MIP values obtained by each method for each subject (First value + Last value /2); Y axis: Difference between the last and first MIP value obtained by each method for each subject (Last value–First value); UL: Upper limit; LL: Lower limit.

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difference between the paired measures was up to 49.6 cmH₂O. For MIP_uni, the repeatability coefficient between measurements was lower, with less dispersion between the measurements (17.1 cmH₂O for evaluator A and 21.8 cmH₂O for evaluator B). The better repeatability of MIP_uni can be explained by a lesser coordination between subject and evaluator and a lesser learning effect [19].

Limitations
A major limitation in our study was that MIP_sta was performed using a mouthpiece with a 2-mm diameter air-leak opening while in MIP_uni there was no air-leak opening in the face mask. Even though the use of an air-leak opening in the interface is recommended, this issue remains controversial in the literature. In a previous study, Smyth et al. [30] showed that the creation of a needle leak in the mouthpiece (18 gauge) had no effect on MIP for the prevention of glottis closure and artifactually high MIP. The authors suggest that careful instruction and observation of the subject may be more valuable than reliance on a small leak in the mouthpiece to prevent glottis closure. In the present study, a rigorous monitoring of the subjects was carried out in order to disregard maneuvers with evident signs of muscle contractions of the mouth and pharynx, rather than inspiratory muscles. In addition, our results showed a difference of more than 20 cmH₂O for various individuals, even higher than 30 cmH₂O in 6 subjects. It is very unlikely that such difference is due only to the absence of the air-leak opening. On the other hand, if the superiority of MIP_uni had been only due to the absence of the air-leak, we would not have observed individuals with lower MIP_uni values in relation to MIP_sta, which is not true. We had around 6 individuals with lower MIP_uni values. Nevertheless, it is essential to conduct further studies aiming to verify the real influence of different sizes of orifices in determining MIP_uni. Furthermore, the majority of subjects reported discomfort due to the interruption of inspiratory flow during MIP_uni, which can be confirmed by higher values of discomfort evaluated quantitatively by the Discomfort Scale. However, only one subject reported mild headache after the test. Although no significant adverse effects were observed during maneuvers, future studies should be conducted to assess the feasibility and safety of this method in different clinical situations and comorbidities. In mechanically ventilated patients, Marini et al. [17] demonstrated that approximately 10 respiratory efforts or a 20-second rest period are needed after airway occlusion to obtain MIP_uni. Further studies should investigate if a 20-second period is actually required to obtain MIP_uni in subjects under spontaneous breathing without artificial airway. A shorter time of attachment could minimize discomfort during this method.

Conclusions
According to the present study results, it is evident that the evaluation by MIP_sta underestimates the inspiratory effort in patients without artificial airway. In this context, we recommend the use of MIP_uni to determine the strength of inspiratory muscles in individuals under spontaneous breathing without artificial airway, since this method presented higher MIP values, high inter- and intraobserver reproducibility and higher repeatability when compared to MIP_sta. Considering that the normal reference values available [14–16] were determined by using MIP_sta, further studies will have to establish new reference values of normality using MIP_uni.

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Wellington P. Yamaguti presented preliminary study results in abstract form at the European Respiratory Society Annual Congress, held September 1–5, 2012, in Vienna, Austria.
Author Contributions
Conceived and designed the experiments: STG ML ALPA CMMB WPY. Performed the experiments: STG KYMK EMOA ML WPY. Analyzed the data: STG ALPA CMMB WPY. Contributed reagents/materials/analysis tools: STG WPY. Wrote the paper: STG KMYK EMOA ML ALPA CMMB WPY.

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