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# How much occlusion time is necessary to assess maximal inspiratory pressure by the unidirectional expiratory valve method in subjects without artificial airway?

*Quanto tempo de oclusão é necessário para avaliar a pressão inspiratória máxima pelo método da válvula expiratória unidirecional em sujeitos sem via aérea artificial?*

*¿Cuánto tiempo de oclusión es necesario para evaluar la presión inspiratoria máxima por el método de la válvula espiratoria unidireccional en sujetos sin vía aérea artificial?*

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**ABSTRACT |** The aim of this study was to determine how much occlusion time is necessary to obtain maximal inspiratory pressure (MIP) by the unidirectional expiratory valve method in subjects without artificial airway. Thirty-one subjects aged 18-60 years were evaluated. MIP was evaluated by the standard method ($MIP_{stan}$) and by the unidirectional expiratory valve method $MIP_{uni}$, with the order of evaluation determined randomly by lot. For $MIP_{uni}$ measurement, a digital vacuum manometer was attached to a unidirectional expiratory valve and an orofacial mask for 20 seconds of occlusion. During this period, all subjects were encouraged to make maximal respiratory efforts. To define the optimum duration of the maneuver, the 20 seconds of effort were partitioned at every five-second interval (0-5s, 0-10s, 0-15s, 0-20s). The time intervals for obtaining $MIP_{uni}$ were compared with the one-way ANOVA test. The mean values of the standard method and the unidirectional expiratory valve method were compared using the paired Student's t-test. The significance level was established at 5%. The mean values for the $MIP_{stan}$ (-102.5±23.9 cmH2O) presented a statistically significant difference as compared to the mean values for $MIP_{uni}$ (-117.3±24.8 cmH2O; p<0.001). Maximal peak values for $MIP_{uni}$ were achieved within the 20-second time window, which differed significantly from the peak values obtained during the first five seconds (p=0.036). The occlusion time necessary to record MIP by the unidirectional expiratory valve method in collaborative subjects without artificial airway should be of at least 20 seconds.

**Keywords |** Maximal Respiratory Pressures; Respiratory Muscles; Muscle Strength.

**RESUMO |** O objetivo desse estudo foi determinar o tempo de oclusão necessário para avaliar a pressão inspiratória máxima (PIMáx) obtida pelo método da válvula expiratória unidirecional em sujeitos sem via aérea artificial. Foram avaliados 31 sujeitos, com idade entre 18 e 60 anos. A PIMáx foi avaliada pelo método convencional ($PIMáx_{conv}$) e pelo método da válvula

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expiratória unidirecional ($PIMáx_{uni}$), sendo a ordem de avaliação definida por meio de sorteio. Para a medida da $PIMáx_{uni}$, um manovacuômetro digital foi acoplado a uma válvula expiratória unidirecional e máscara orofacial por 20 segundos de oclusão. Nesse período, todos os sujeitos foram encorajados a realizar esforços inspiratórios máximos. Para definir a ótima duração da manobra, o tempo de esforço foi dividido a cada intervalo de 5 segundos (0-5s, 0-10s, 0-15s, 0-20s). Os intervalos de tempo para obtenção da $PIMáx_{uni}$ foram comparados por meio do teste de ANOVA One-way. Para comparação das médias dos valores de $PIMáx_{conv}$ e $PIMáx_{uni}$, foi utilizado o teste t de Student. O nível de significância foi de 5%. A média dos valores da $PIMáx_{conv}$ foi de -102,5±23,9 $cmH_2O$, enquanto que a $PIMáx_{uni}$ foi de -117,3±24,8 $cmH_2O$ (p<0,001). O valor absoluto máximo da $PIMáx_{uni}$ foi alcançado dentro do intervalo de 0-20 segundos, que foi significativamente superior ao valor absoluto máximo obtido nos primeiros 5 segundos (p=0,036). O tempo de oclusão necessário para avaliar a PIMáx pelo método da válvula expiratória unidirecional em sujeitos colaborativos sem via aérea artificial deve ser de pelo menos 20 segundos.

**Descritores** | Pressões Respiratórias Máximas; Músculos Respiratórios; Força Muscular.

**RESUMEN** | Este estudio busca determinar cuánto tiempo de oclusión es necesario para obtener la presión inspiratoria máxima (PIMáx) por medio del método de la válvula espiratoria unidireccional en individuos sin vía aérea artificial. Se evaluaron 31 sujetos de entre 18 y 60 años de edad. La PIMáx se evaluó mediante el método estándar ($PIMáx_{est}$) y el método de válvula espiratoria unidireccional ($PIMáx_{uni}$), siendo que el orden de evaluación se estableció por medio de un sorteo. Para el $PIMáx_{uni}$, un manovacuómetro digital se ha conectado a una válvula espiratoria unidireccional y una máscara orofacial durante 20 segundos de oclusión. Durante este período, se alentó a los individuos a hacer esfuerzos respiratorios máximos. Para definir la óptima duración de la maniobra, el tiempo de esfuerzo se dividió en intervalos de cinco segundos (0-5s, 0-10s, 0-15s, 0-20s). Los intervalos del tiempo para el $PIMáx_{uni}$ se compararon mediante la prueba ANOVA one-way. Las medias de los valores de $PIMáx_{est}$ y de $PIMáx_{uni}$ se compararon mediante la prueba pareada t de Student. El nivel de significancia se estableció en el 5%. La media de los valores de $PIMáx_{est}$ (-102,5±23,9 cmH2O) presentó una diferencia estadísticamente significativa en comparación con la media de los valores de $PIMáx_{uni}$ (-117,3±24,8 cmH2O, p<0,001). El valor absoluto máximo obtenido de $PIMáx_{uni}$ estaba dentro del intervalo de 0-20 segundos, que fue significativamente superior del valor absoluto máximo durante los primeros 5 segundos (p=0,036). El tiempo de oclusión necesario para registrar la PIMáx por el método de válvula espiratoria unidireccional en individuos colaborativos sin vía aérea artificial debe ser de al menos 20 segundos.

**Palabras clave** | Presiones Respiratorias Máximas; Músculos Respiratorios; Fuerza Muscular.

## INTRODUCTION

The most common method for assessment of inspiratory muscle strength is performed by measuring the negative pressure generated in the mouth during maximum inspiration against an occluded airway, after a forced expiration close to the residual volume ($MIP_{stan}$)[1,2]. Although it is considered an easily performed and well tolerated method by the patients, its measurement depends on the understanding and collaboration of the individuals to carry out really maximal inspiratory efforts[3,4].

To overcome the need for collaboration during the evaluation of $MIP_{stan}$, Marini, Smith and Lamb[5] developed a technique that optimizes the inspiratory effort of critically ill and poorly collaborative patients submitted to invasive mechanical ventilation, through the use of a unidirectional expiratory valve, in which expiration is allowed without resistance and inspiration is occluded ($MIP_{uni}$). As a consequence of a physiological response (increased respiratory drive after a prior insufficient inspiration), the patient initiates successive inspiratory efforts from volumes progressively closer to the residual one, generating increasingly negative inspiratory pressures[5,6]. Later studies[7,8] confirmed that the unidirectional expiratory valve method optimizes the maximum capacity of action of inspiratory muscles as they demonstrated that $MIP_{uni}$ values were significantly higher than $MIP_{stan}$.

Regarding the inspiratory occlusion time during the unidirectional expiratory valve method in patients undergoing mechanical ventilation, Marini, Smith and Lamb[5] recommend a period of at least 20 seconds to 25 seconds to obtain $MIP_{uni}$. However, this time seems to be insufficient to determine maximum values in patients with changes in level of consciousness[9,10]. In non-cooperative patients, higher $MIP_{uni}$ values are obtained with 40-second occlusion[11,12]. There is a literature report of obtaining $MIP_{uni}$ in even greater time, attaining the peak between 40 seconds and 60 seconds of occlusion[13].

In collaborative patients without altered level of consciousness and under spontaneous breathing without artificial airway, the unidirectional expiratory valve method was adapted by means of a non-invasive interface using an orofacial mask[14]. In this study, the $MIP_{uni}$ method also presented superiority in the optimization of inspiratory effort, besides having greater repeatability as compared to the conventional method[14]. However, the occlusion time required to obtain $MIP_{uni}$ in this population is still unknown. In view of this context, the present study aimed to determine the necessary occlusion time to evaluate $MIP_{uni}$ in collaborative subjects without artificial airway.

## METHODOLOGY

### Subjects

Thirty-one individuals who met the following criteria were included: age between 18 and 60 years; normal lung function test (FVC and $FEV_1$ ≥80% predicted and $FEV_1$/FVC≥0.7); nonsmoker; having no diagnosis of cardiopulmonary disease and having not previously been assessed by any of the methods tested in the study. Inability to carry out the evaluations within the criteria of technical acceptability was considered as exclusion criterion. The study was approved by the Ethics Committee for Research with humans of the Hospital Sírio-Libanês (HSL2011/17) and all participants signed an informed consent form.

### Study design

This is a cross-sectional study whose subjects were submitted to evaluation of personal history and life habits through a questionnaire, anthropometrics, pulmonary function test, and assessment of inspiratory muscle strength through measurement of $MIP_{stan}$ and $MIP_{uni}$.

### Pulmonary function test

Pulmonary function testing was performed using a portable spirometer (model Koko Pftesting; nSpire Healthy; Longmont; Colorado; USA), previously calibrated according to the American Thoracic Society recommendations[15]. The highest values for each spirometric variable were considered, which are expressed in absolute values and as percentages of predicted values of normality, according to those determined by Pereira et al[16].

### $MIP_{stan}$ and $MIP_{uni}$

For evaluation of both $MIP_{stan}$ and $MIP_{uni}$, we used a digital manovacuometer with an operating range of ± 300 $cmH_2O$ (model MVD300, Microhard, Porto Alegre, RS, Brazil). The order for application of the methods was previously defined randomly by lot and stratified according to gender. A rest of at least 20 minutes was allowed between each evaluation method. The evaluator in charge of instruction and execution of the procedures remained blind to the results obtained.

Measurement of MIP followed the recommendations of the guidelines of the Brazilian Society of Pulmonology and Tisiology[4], using a digital manovacuometer coupled to a mouthpiece, with a two millimeters in diameter orifice. To obtain the MIP, subjects were encouraged to perform a maximum inspiratory effort from a volume close to the residual. Ten repetitions of this maneuver were performed, with an interval of one minute between the efforts, aiming to obtain three acceptable maneuvers (no leaks and lasting for at least two seconds) and at least two repeatable maneuvers among them (i.e. with values that did not differ by more than 10% from the highest value). The $MIP_{stan}$ value considered for the study was the highest obtained between the repeatable maneuvers.

The evaluation of $MIP_{uni}$ was performed using the digital manovacuometer coupled to a unidirectional expiratory valve and orofacial mask. The subjects were placed in a comfortable chair and remained with the mask manually coupled by the evaluator for 20 seconds of valve occlusion. During this time, the study subjects were asked to perform maximal inspiratory and expiratory efforts. This maneuver was repeated three times and the highest value obtained at the end of a maneuver was considered as the measure of $MIP_{uni}$.

### Scale of discomfort

The discomfort caused during $MIP_{uni}$ evaluation was measured by a numerical scale of 10cm, where "zero" corresponded to "no discomfort" and "ten" corresponded to "maximum discomfort"[17].

### Statistical analysis

The data were analyzed with SPSS for Windows, version 17.0 (IMB SPSS Statistics, IBM, Armonk, New York, USA), and treated with descriptive (mean

and standard deviation) and inferential analyses. The Shapiro-Wilk test was used to verify the normality and homogeneity of data variance. Student's t-test was used to compare the mean values of $MIP_{stan}$ and $MIP_{uni}$.

In the method of unidirectional expiratory valve, to determine the optimal duration of the maneuver to obtain $MIP_{uni}$, the inspiratory effort time was partitioned at every five-second interval (0-5s, 0-10s, 0-15s, 0-20s). The time intervals of the unidirectional expiratory valve method were compared using one-way ANOVA. The level of significance adopted for statistical analysis was 5% ($p<0.05$).

### Calculation of the sample

A sample of 22 subjects was determined using prior study results[5] to detect a difference in $MIP_{uni}$ of 24.8±24.5 $cmH_2O$, when a 5-second occlusion time was compared with 20-second occlusion time (error of 5% and statistical power of 90%).

## RESULTS

Thirty-one individuals were evaluated, with a mean age of 30.8±6.2 years. The sample characteristics are summarized in Table 1.

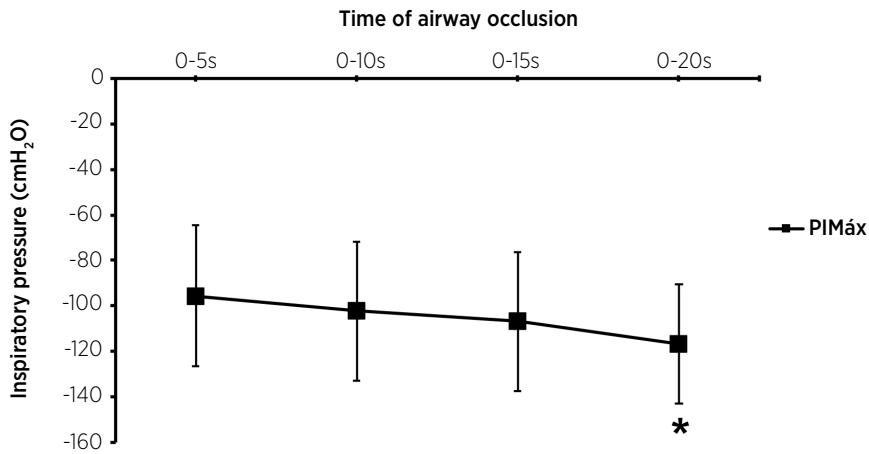
The mean of $MIP_{uni}$ values (-117.3±24.8 $cmH_2O$) was higher than that of $MIP_{stan}$ (-102.5±23.9 $cmH_2O$), with a statistically significant difference between these values ($p<0.001$).

Regarding inspiratory occlusion time during the unidirectional expiratory valve method, we observed that $MIP_{uni}$ values during a 20-second occlusion (-116.7±26.3 $cmH_2O$) were significantly higher (a difference of 22. 1%) than those obtained in the first five seconds (-95.6±31 $cmH_2O$, $p=0.036$) (Graph 1). The discomfort caused by the procedure presented values of 5.7±2.8cm, according to the Discomfort Scale (minimum value of 0.1cm and maximum value of 10cm), and 32.3% of the sample reported intense discomfort, above 7cm in the scale, and 71% presented discomfort above 5cm (Graph 2).

Table 1. Characteristics of the study population

| Variables | | Mean±standard deviation (variation) (n = 31) |
|---|---|---|
| Sex | Male | 14 |
| | Female | 17 |
| Age years) | | 30.80 ± 6.2 (21-49) |
| BMI ($kg/m^2$) | | 24.5±3.5 (17.9-29.9) |
| Pulmonary function | FVC (%pred) | 92.4±12.1 (80-127) |
| | $FEV_1$ (%pred) | 93. 10.6 (80-124) |
| | $FEV_1$/FVC (%pred) | 101.0±7.2 (87-114) |
| | FEF 25-75% (%pred) | 95.1±21.1 (61-145) |
| | VC (%pred) | 90.1±11.1 (76-117) |
| | IC(L) | 2.95±0.63 (1.81-6.58) |
| | ERV (L) | 1.02±0.45 (0.09-1.79) |

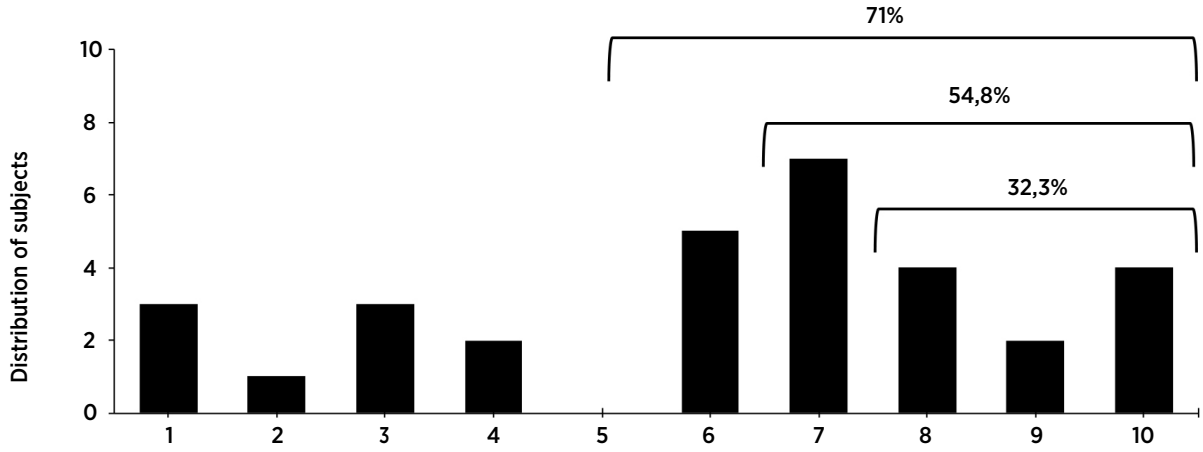
Variation: minimum value – maximum value; n: number of individuals; BMI: body mass index; kg: kilograms; m: FVC meters (% pred): percentage of predicted for forced vital capacity; $FEV_1$(%pred): percentage of predicted for forced expiratory volume in the first second; FEF 25-75% (%pred): percentage of predicted for flow between 25 and 75% of FVC curve; CV (%pred): percentage of predicted for vital capacity; IC: inspiratory capacity; ERV: expiratory reserve volume; L: liters.




Graph 1. Time of airway occlusion to obtain $MIP_{uni}$

$MIP_{uni}$: unidirectional expiratory valve method.

* Statistically significant difference when compared to the 0-5 seconds period ($p = 0.036$).




Graph 2. Discomfort caused by $MIP_{uni}$ evaluation
$MIP_{uni}$: unidirectional expiratory valve method

## DISCUSSION

The present study aimed to determine the occlusion time required to evaluate $MIP_{uni}$ in collaborative subjects without artificial airway. The results showed that an occlusion time of at least 20 seconds was necessary to obtain $MIP_{uni}$, since there was a 22.1% variation in $MIP_{uni}$ values when comparing 5 seconds with 20 seconds of occlusion, a difference considered clinically and statistically significant.

In patients undergoing invasive mechanical ventilation, Marini et al.[5] recommend that the occlusion time in the unidirectional expiratory valve method should be maintained for at least 20 to 25 seconds , in order to obtain $MIP_{uni}$. From among possible explanations, this occlusion time would be required to increase the respiratory drive and mechanical efficiency during maneuvers, which would thereby cause increased inspiratory muscle effort. In patients with altered levels of consciousness and reduced respiratory drive prior to occlusion, the required occlusion time seems to be even greater[9,10], as an alternative to verbal stimulation in those patients who do not interact adequately with the examiner. Later studies confirmed this hypothesis, demonstrating that in non-cooperative patients, higher $MIP_{uni}$ values were obtained with occlusion of 40 seconds to 60 seconds[11-13].

A previous study of our research group was the first to evaluate the use of the unidirectional expiratory valve method in collaborative subjects under spontaneous breathing without artificial airway[14]. However, the necessary occlusion time had not been determined. The present study demonstrated that an occlusion time of at least 20 seconds was required. It is important to note that all participants in the study were fully healthy without any disease or condition that could alter the respiratory drive or level of understanding prior to assessment. In addition, all of the patients were verbally encouraged to perform maximal inspiratory and expiratory efforts during the 20-second occlusion time. Therefore, to perform an occlusion time greater than 20 seconds does not seem to be necessary for this population.

In addition, although no adverse effects were observed during the maneuvers, the discomfort caused by the inspiratory blockage may be a limiter for a more prolonged $MIP_{uni}$ evaluation in individuals with an intact level of consciousness, such as those included in the present study. In patients with an artificial airway with a score equal to 15 points on the Glasgow coma scale, the mean occlusion time was 23.8 seconds, close to the occlusion time of the present study. Authors have also reported that patients did not tolerate longer time and that they reached the plateau more rapidly after three consecutive inspirations[10].

Importantly, 32.3% of the sample reported severe discomfort, above 7 cm in the Discomfort Scale, and 71% presented moderate to severe discomfort, above 5cm. Therefore, an occlusion time exceeding 20 seconds may not be tolerable and viable in clinical practice.

One limitation of this study is that it was not tested in patients without artificial airway, with altered level of consciousness, and non-collaborative. According to results of previous studies in intubated patients, this population could have greater tolerance and need for superior occlusion time to obtain $MIP_{uni}$.

## CONCLUSION

Given the above, it is concluded that the time needed to evaluate $MIP_{uni}$ in collaborative subjects without artificial airway must be of at least 20 seconds.

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