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# Efficiency of physiotherapy with Caycedian Sophrology on children with asthma: A randomized controlled trial

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#### **Abstract**

Background: Asthma is the most common chronic disease in pediatrics. Along with the usual drug therapy using corticosteroids and bronchodilators, some interest has been shown for adjuvant therapies, such as sophrology. However, the level of evidence for non-pharmaceutical therapies in asthma remains low, especially in children. This study aimed to assess whether in children with asthma, peak expiratory flow (PEF) improved more after a sophrology session alongside standard treatment than after standard treatment alone.

**Methods:** We carried out a prospective randomized controlled clinical trial among 74 children aged 6-17 years old, hospitalized for an asthma attack. Group 1: conventional treatment (oxygen, corticosteroids, bronchodilators, physiotherapy) added to one session of sophrology. Group 2: conventional treatment alone. The primary outcome was the PEF variation between the initial and final evaluations (PEF<sub>2</sub>-PEF<sub>1</sub>).

**Results:** Demographic and clinical characteristics were similar in both groups at baseline. Measures before and after the sophrology session showed that the PEF increased by mean 30 L/min in the sophrology group versus 20 L/min in the control group (P = 0.02). Oxygen saturation increased by 1% versus 0% (P = 0.02) and the dyspnea score with visual analogue scale improved by two points point (P = 0.01). No differences were observed between the two groups in terms of duration of hospitalization, use and doses of conventional medical treatment (oxygen, corticosteroids, and bronchodilators), and quality of life scores.

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**Conclusions:** Sophrology appears as a promising adjuvant therapy to current guideline-based treatment for asthma in children.

#### KEYWORDS

asthma, peak expiratory flow, pediatrics, physiotherapy, sophrology

# 1 | INTRODUCTION

Asthma is the most prevalent chronic disease in pediatrics, physiologically defined as a respiratory discomfort at expiration with inflammation of the bronchial epithelium, bronchospasm, and bronchial hyperactivity. Along with the usual drug therapy using corticosteroids and bronchodilators, many adjuvant therapies have been developed for asthma treatment. Although not consensual, respiratory physiotherapy is sometimes used in asthmatic patients, sometimes improving their quality of life. In children, drainage techniques vary from one, team to another. Other adjuvant therapies have also been used in asthma, such as hypnosis, felaxation, felax massages, group sessions with alternative therapies, and sophrology. These techniques focus on the psychological factors contributing to asthma attacks.

However, the scientific validation of these adjuvant therapies' efficacy has been extremely lacking. Long et al<sup>28</sup> suggested that stress management techniques could improve respiratory function. Similarly, Alexander et al<sup>11</sup> showed an increase of 22 L/min in peak expiratory flow (PEF) after a relaxation session in asthmatic children, while the PEF decreased in the control group.

Sophrology is based on breathing, which is the only vital function that is automatic and can become conscious at any time. It comes from ancient Greek σωζ ("harmony,") φρην ("mind"), and -λογία ("study/ science"). Therefore, sophrology is the "study of the consciousness in harmony." Professor Alfonso Caycedo, a Colombian neuro-psychiatrist, developed the method in the 1960's, through his personal, and professional experiences. He presented in 1970 at the first International Sophrology Conference as an attempt to scientifically study the human consciousness, both as a philosophy and a way of life, as well as a therapy and a personal development technique. Pr Caycedo stated: "sophrology is learning to live." This healthcare philosophy is based on the study of human consciousness and of the relation between body and mind. It requires a structured method consisting in very practical physical and mental exercises, using techniques such as concentration, deep breathing, relaxation, visualization, and simple movements. Sophrology is more and more used as an adjuvant therapy to treat pain and/or anxiety in oncology, <sup>29,30</sup> geriatrics, <sup>31</sup> obstetrics, <sup>32,33</sup> and dentistry.<sup>34</sup> The randomized controlled trial from Constant et al<sup>35</sup> found a positive impact of sophrology on non-invasive ventilation tolerance in adult patients with acute respiratory failure.

However, no scientific evidence is available regarding the efficiency of sophrology in children with asthma. Yet, during an

asthma attack, children are stressed, in pain, tense, or simply uncomfortable.

This study aimed to assess whether, in children with asthma, PEF improved more following a sophrology session alongside standard treatment, than after standard treatment alone.

## 2 | METHODS

# 2.1 | Study design and population

This open-label randomized controlled trial was carried out in the tertiary care pediatric pulmonology Department of Montpellier University Hospital, France. All children aged 6-17 years, who were hospitalized for an asthma attack between November 2013 and March 2016, were assessed for eligibility. An asthma attack includes several signs: severe shortness of breath, chest tightness or pain, coughing or wheezing, low PEF values, and symptoms that fail to respond to use of a quick-acting (rescue) inhaler. Children with severe complications requiring intensive care unit transfer were not eligible. We did not approach eligible patients when logistic problems would compromise the research (hospitalization during the week-end, both sophrologists unavailable).

All included patients were randomized, into either the sophrology group or into the control group.

# 2.2 | Formal aspects

The study was conducted in compliance with the Good Clinical Practices protocol and Declaration of Helsinki principles. It was approved by the South Mediterranean IV Ethics Committee (2013-A00581-44) and registered on ClinicalTrials.gov (NCT02114398). Informed consent was obtained from all parents.

# 2.3 | Interventions

In both groups, a physiotherapy session was performed in the morning by a physical therapist of our department who was not a sophrologist. In the sophrology group, a 1-h sophrology session was performed after the physiotherapy session. In order to limit the variability and subjectivity inherent in the sophrology technique, two different sophrologists (HR, FC) were in charge of the sessions according to their work schedule, and neither of them participated in the outcomes measurements. Both interventions (sophrology and physiotherapy) occurred on the day following the admission.

The physiotherapy session lasted about 30 min. After a bronchial auscultation, upper airways were de-obstructed with a physiological saline solution, when necessary. Then, directed ventilation (breathing exercises) was performed to improve the respiratory mechanics, followed, when required, by a bronchial drainage to evacuate secretions, with more or less help with the expectoration. The session ended with therapeutic education for appropriate use of the peak flow meter, asthma attack management, better exhaling, good adherence to

medication treatments, and using inhalers.

The sophrology session lasted about 1h. The first part of the session, lasting about 15 min, started with a discussion ("pre-sophronic dialogue") aimed at creating a climate of confidence. It included a brief presentation of sophrology and questions to the patient about his or her tastes, interests and activities. Then the main part of the session, of approximately 30 min, used a slow and monotone-directed speech, leading the patient to a level between awakening, and sleep ("sophroliminal level"). This relaxation session aimed at facilitating "letting go,"

leading the patient to a level between awakening, and sleep ("sophroliminal level"). This relaxation session aimed at facilitating "letting go," focusing on body sensations, and improving the well-being ("sophronization of vital base"). The techniques were adapted to the child's age, availability, and fatigue. Lastly, the session ended with a final discussion ("post-sophronic dialogue"), putting into words the different sensations felt without any judgment or interpretation ("pheno-description").

### 2.4 | Randomization

Randomization was carried out using a computer-generated list of random numbers with permuted-block, 1:1 ratio, varying block sizes, and stratification by age (6-11 and 12-17 years) and asthma severity (intermittent/mild persistent and moderate persistent/severe persistent). Allocation concealment was achieved by a centralized randomization procedure through an electronic case-report form.

# 2.5 | Outcomes

# 2.5.1 | Peak expiratory flow (PEF)

The PEF is a primary tool used in assessing asthma attacks and monitoring airway changes in children above the age of 5. The PEF was measured with a peak flow meter. All children received the same therapeutic education and all measurements were performed under the supervision of a trained physical therapist. The PEF value was directly indicated by the position of the ruler in the meter. Three measures were systematically taken, and the highest value was recorded. The percentage of predicted

The PEF was measured in both groups, first in the morning before the physiotherapy session (PEF $_1$ ) and then in the afternoon, 6 h later (PEF $_2$ ). The primary outcome was the PEF variation between the initial and final evaluations (PEF $_2$ -PEF $_1$ ).

value was calculated using pediatric reference PEF values.<sup>37</sup>

# 2.5.2 | Visual analogue scale (VAS)

The general state of the child was assessed using a face VAS with values from 0 (indicating very well) to 10 (indicating very bad), and

answering five questions regarding physical health, fatigability, bronchial obstruction, dyspnea, and coughing. A physical therapist measured the VAS for each question, first in the morning before the physiotherapy session (VAS $_1$ ) and then in the afternoon, 6 h later (VAS $_2$ ). For each question, variation between the initial and final evaluations (VAS $_2$ -VAS $_1$ ) was measured.

# 2.5.3 | Quality of life

Quality of life was assessed before discharge from the hospital using the generic PedsQL questionnaire, with ratings by the children themselves, and by their parents (proxy-version).<sup>39</sup> This instrument evaluates health-related quality of life in four dimensions (physical functioning, emotion functioning, social functioning, and school functioning). Each item uses a five-point Likert scale from 0 (never) to 4 (almost always). Items are reverse-scored and linearly transformed to a 0-100 scale, with higher scores indicating a better QoL.

After translation and cultural adaptation, the psychometric properties of the French version of the PedsQL appeared to be acceptable. The French self- and proxy-versions versions of the questionnaire were used for various age groups: 5-7, 8-12, or 12-18 years.

# 2.5.4 Other clinical characteristics

Asthma severity was categorized into four classes, and an asthma control level defined by the GINA guidelines (www.ginasthma.org) was collected at baseline.<sup>41</sup> Asthma control was assessed using the asthma control test (ACT), with versions adapted to children 11 years of age or younger, and to children 12 years or older.<sup>42,43</sup>

We collected oxygen saturation readings (SpO $_2$ ), hospitalization duration, oxygen flow (L/min), overall oxygen consumption during hospitalization (oxygen flow × delivery time), and asthma treatments (beta2-adrenergic agonists, corticosteroids) during hospitalization.

The families of all children hospitalized for asthma attack in our department are offered to participate in a therapeutic education group session, usually one month after hospital discharge. As part of this clinical trial, we collected this information about the actual participation in this education program.

# 2.6 | Sample size and statistical analysis

To calculate the sample size, we hypothesized that the PEF would increase by 5% (standard deviation 12%) in the control group and by 12% in the sophrology group. <sup>11</sup> With a power of 80% and a bi-lateral alpha risk of 5%, we planned to include 37 children in each group.

Quantitative variables were described with means and standard

deviation or median and inter-quartile range, and qualitative variables were described with frequencies. Quantitative variables were compared with the parametric Student's t-test when the distribution was Gaussian and with the Mann-Whitney test otherwise. Qualitative variables were compared with the Chi-square

test or Fisher's exact test, as appropriate. The analysis of our primary

and secondary endpoints was supplemented by a multivariate analysis using a logistic regression model adjusting for clinical severity, age, and gender.

Analyses were performed in accordance with the intention-to-treat principle. The two-sided significance level was 0.05. The SAS version 9 (SAS Institute, Cary, NC) was used.

# 3 | RESULTS

control levels

# 3.1 | Study participants

hospitalized for an asthma attack in our department. Twelve children were not eligible because of complications requiring intensive care unit transfer. Because of the logistic issues mentioned before, 145 children were not approached to participate in the study. Two families refused to participate. A total of 74 children were included and randomized in the sophrology (N = 37) or control group (N = 37). All of them received

the allocated treatment and had PEF measurements before and after

the intervention. Patients' characteristics at baseline are described in

Table 1. The two groups did not differ in any of the measured

demographic and clinical variables, especially asthma severity, and

During the study period, 169 children aged 6-17 years old were

## 3.2 | Clinical endpoints variation

Variations in clinical endpoints between the initial and final evaluations are shown in Table 2. PEF, dyspnea VAS level, and oxygen saturation improved significantly in the sophrology group compared to the control group (Figure 1). Variations in heart rate and respiratory rate did not differ between groups. Adjusting for clinical severity, age, and gender did not change the results. Patients of the sophrology group had a two-times greater chance of reaching a 30-L/min increase in PEF (adjusted odd ratio (OR): 1.9; 95% confidence interval (CI): 1.0-3.7; P = 0.05) and a 2% increase in oxygen saturation (adjusted OR: 2.2; 95%CI: 1.1-4.2; P = 0.02), but no improvement was found for heart rate, and respiratory rate.

# 3.3 | Other clinical outcomes

Sonbrology group

mean length of hospital stay  $(2.78 \pm 1.37 \text{ days vs } 2.73 \pm 1.77 \text{ days},$  P = 0.53, respectively) and overall median consumption of oxygen  $(1.57 \ [0.5-4] \ L/min \ vs \ 1.75 \ [0.5-5] \ L/min,$  P = 0.97, respectively). Consumption of beta2-adrenergic agonists, and corticosteroids during hospitalization did not differ between groups, whatever the form used. Median consumption of salbutamol in sophrology and control groups was 55 mg (interquartile range 32-85) and 50 mg (30-100),

Control group

The sophrology group and the control group did not differ in terms of

**TABLE 1** Baseline characteristics of study participants

N

	N	Sophrology group	N	Control group
Gender (boys)	37	23 (62)	37	22 (59)
Age (years)	37	9.2 (2.8)	37	9.8 (2.7)
Height (cm)	37	132.9 (15.6)	37	138.7 (16.5)
Weight (kg)	37	32.8 (15.0)	37	34.6 (16.7)
Asthma severity	37		37	
Intermittent/mild		31 (84)		30 (81)
Moderate persistent/severe persistent		6 (16)		7 (19)
Asthma control	37	17.7 (5.0)	34	17.5 (4.8)
Heart rate (bpm)	37	113.4 (16.9)	37	118.1 (16.7)
Respiratory rate (cycle/min)	37	23.8 (6.4)	37	25.3 (6.8)
Systolic blood pressure (mmHg)	34	109.0 (11.0)	34	111.0 (10.4)
Diastolic blood pressure (mmHg)	34	58.2 (7.3)	34	60.8 (8.2)
PEF (L/min)	37	162.2 (64.8)	37	184.7 (77.1)
Percentage of predicted PEF (%)	37	71.4 (21.3)	37	72.4 (24.0)
SpO2 (%)	36	96.4 (1.9)	36	96.6 (1.8)
VAS				
Physical health	37	1.7 (1.9)	37	2.0 (2.4)
Fatigability	37	2.6 (2.6)	37	3.4 (3.0)
Bronchial obstruction	37	3.2 (2.6)	37	3.5 (2.9)
Breathlessness/dyspnea	37	2.8 (2.6)	37	2.4 (2.6)
Coughing	37	3.5 (2.5)	37	3.6 (2.8)

Values are mean (SD), median (Q25-Q75), or N (%); bpm, beats per minute; PEF, peak expiratory flow; SpO<sub>2</sub>, oxygen saturation; VAS, visual analogue scale (0-well to 10-bad).

**TABLE 2** Variations in clinical endpoints between initial and final evaluations

Variations (final-baseline)	N	Sophrology group median (Q25; Q75)	N	Control group median (Q25; Q75)	P-value
PEF (L/min)	37	30 (15;50)	37	20 (0;30)	0.02
SpO2 (%)	36	1 (0;3)	36	0 (0;3)	0.02
Oxygen flow (L/min)	4	-1 (-1.5;-0.3)	6	-0.3 (-0.5;0.8)	0.09
Heart rate (bpm)	37	-1 (-10;4)	36	-6 (-16;-1.5)	0.09
Respiratory rate (cycle/min)	37	0 (-4;2)	35	-2 (-4;4)	0.67
VAS					
Physical health	37	-1 (-2;0)	37	0 (-2;0)	0.27
Fatigability	37	0 (-2;0)	37	0 (-2;0)	0.78
Bronchial obstruction	37	-2 (-4;0)	37	0 (-4;0)	0.14
Breathlessness/dyspnea	37	-2 (-4;0)	37	0 (-2;0)	0.01
Coughing	37	-2 (-4;0)	37	-2 (-2;0)	0.44

PEF, peak expiratory flow; SpO<sub>2</sub>, oxygen saturation; bpm, beats per minute; VAS, visual analogue scale (0-well-10-bad). Significant *P* values <0.05 are marked in bold.

respectively, for nebulizers (P = 0.95) and 1000 mg (500-1200) and 675 mg (500-1200), respectively, for inhalers (P = 0.55). The median consumption of prednisone was 20 mg per day (interquartile range 20-50 mg), in both groups (P = 0.87).

One month after hospital discharge, we found no significant difference in terms of participation in our asthma education program: 35% of the children in the sophrology group and 45% in the control group (P = 0.8).

# 3.4 | Quality of life

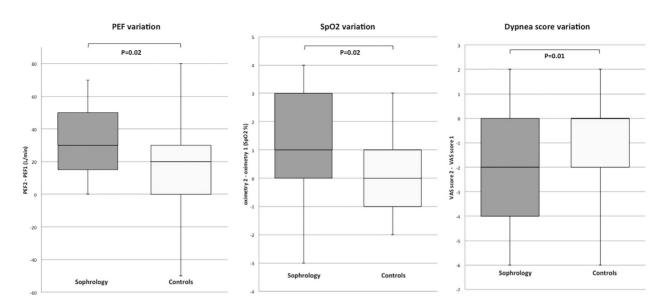
The quality of life scores were not significantly different between the sophrology and the control groups, overall  $(72.6 \pm 12.1 \text{ vs } 73.4 \pm 13.7,$ 

P = 0.8, respectively), in each sub-group by age (5-7, 8-12, and 13-18 years old), and in self and proxy-reports (Table 3).

#### 4 | DISCUSSION

This study is one of the very few randomized controlled pediatric clinical trials evaluating a non-pharmacologic therapy in asthma, and the first one involving sophrology.

We intended to objectively assess the impact of sophrology on asthma and successfully included the expected number of 74 children planned in the study design. Indeed, the enthusiasm of families to participate in this study was important and almost none refused to participate. Many participants were in fact disappointed not to be



**FIGURE 1** Variation between baseline and final evaluation: comparison of the two groups. Box plots of the variation of peak expiratory flow (PEF), dyspnea score, and oxygen saturation (SpO2). The bottom and top of the box represent the 25th and 75th percentiles, the band inside the box represents the 50th percentile (median), and the end of the whiskers represents the 5th and 95th percentiles. *P*-values indicate comparison of the variation between sophrology and control groups

8.5											
TABLE 3 Qua Self-reports	ality of	life scores  Sophrology		Controls		Self-reports		Sophrology		Controls	
Overall	N	Mean (±SD)	N	Mean (±SD)	P value	13-18 years-old	N	Mean (±SD)		Mean (±SD)	P value
School	37	67.7 (±15.2)	35	68.4 (±15.5)	0.30	School	5	51.0 (±13.9)	4	71.3 (±19.3)	0.11
Emotion	37	69.9 (±15.6)	35	65.7 (±20.4)	0.33	Emotion	5	67.0 (±16.8)	4	38.8 (±4.8)	0.01
Physical	37	76.8 (±16.0)	35	79.3 (±16.8)	0.38	Physical	5	75.6 (±16.4)	4	69.5 (±14.3)	0.58
Psychosocial	37	70.4 (±11.9)	35	70.2 (±14.3)	0.94	Psychosocial	5	63.7 (±10.8)	4	58.8 (±9.3)	0.49
Relation	37	76.5 (±14.3)	35	76.6 (±21.6)	0.51	Relation	5	73.0 (±8.4)	4	66.3 (±32.0)	0.66
Health	37	76.8 (±16.0)	35	79.3 (±16.8)	0.38	Health	5	75.6 (±16.4)	4	69.5 (±14.3)	0.58
Total	37	72.6 (±12.1)	35	73.4 (±13.7)	0.80	Total	5	67.8 (±12.1)	4	62.5 (±19.8)	0.50
Self-reports						Proxi-reports					
5-7 years old	N	Mean (±SD)	N	Mean (±SD)	P value	Fathers	N	Mean (±SD)	N	Mean (±SD)	P value
School	19	65.8 (±16.4)	8	73.8 (±10.6)	0.22	School	9	66.1 (±25.6)	14	73.2 (±21.0)	0.47
Emotion	19	72.1 (±15.5)	8	80.0 (±14.1)	0.23	Emotion	9	73.9 (±12.4)	14	72.1 (±23.8)	0.84
Physical	19	79.9 (±15.5)	8	93.8 (±6.7)	0.02	Physical	9	85.3 (±12.7)	14	78.2 (±20.7)	0.64
Psychosocial	19	70.5 (±12.8)	8	75.8 (±8.7)	0.29	Psychosocial	9	73.7 (±14.1)	14	76.8 (±18.8)	0.68
Relation	19	73.7 (±15.7)	8	73.8 (±16.9)	0.99	Relation	9	81.1 (±12.7)	14	85.0 (±23.0)	0.15
Health	19	79.9 (±15.5)	8	93.8 (±6.7)	0.02	Health	9	85.3 (±12.7)	14	78.2 (±20.7)	0.64
Total	19	73.8 (±12.6)	8	82.1 (±6.3)	0.09	Total	9	77.7 (±12.8)	14	77.3 (±18.9)	0.95
Self-reports						Proxi-reports					
8-12 years old	N	Mean (±SD)	N	Mean (±SD)	P value	Mothers	N	Mean (±SD)	N	Mean (±SD)	P value
School	13	68.5 (±11.4)	23	66.1 (±16.3)	0.65	School	28	61.7 (±20.1)	23	67.8 (±20.6)	0.29
Emotion	13	67.9 (±16.1)	23	65.4 (±19.2)	0.70	Emotion	28	62.2 (±17.2)	23	63.3 (±18.5)	0.82
Physical	13	72.6 (±16.9)	23	76.0 (±17.1)	0.52	Physical	28	76.6 (±19.4)	23	81.5 (±18.4)	0.38
Psychosocial	13	72.8 (±10.8)	23	70.2 (±15.7)	0.60	Psychosocial	28	67.0 (±13.7)	23	70.1 (±17.1)	0.47
Relation	13	81.9 (±13.2)	23	79.3 (±21.4)	0.96	Relation	28	77.0 (±20.3)	23	79.1 (±22.9)	0.56
Health	13	72.6 (±16.9)	23	76.0 (±17.1)	0.52	Health	28	76.6 (±19.4)	23	81.5 (±18.4)	0.38
Total	13	72.7 (±11.8)	23	72.2 (±14.7)	0.92	Total	28	70.3 (±13.5)	23	74.1 (±15.9)	0.36

randomized into the sophrology group. This likely reflects the							
evolution of society towards alternative non-invasive therapies. 13							
The primary outcome of this trial, that is the PEF, improved by							
30 L/min on average, after a single session of sophrology, significantly							
more than in the control group. At baseline, both groups were							
-t-ti-ti-ti-th-n-t-different in any of the analysis of the ana							

statistically not different in any of the measured variables; therefore this result appears as scientifically relevant.

Asthma attacks are multifactorial, and relaxation techniques seem to positively interact between stress, and bronchospasm. Indeed, the controlled clinical trial from Vasquez et al<sup>8</sup> showed a significant impact of a relaxation program on both the PEF and the duration of the asthma attack, in comparison to a standard self-management program. The other rare existing controlled clinical trials are in line with our results, even though they did not measure any quantitative physiological outcomes: Chiang et al<sup>6</sup> found that relaxation-breathing training decreased anxiety and asthma signs or symptoms in children with moderate-to-severe asthma; and Vedanthan et al<sup>44</sup> measured in a randomized controlled trial a higher relaxation and positive attitude in university students with asthma who practiced yoga.

The dyspnea score after the sophrology session decreased significantly by two points out of 10 on average, in comparison with no change in the control group. This result is in line with that of our primary outcome. Indeed, the level of dyspnea measured with a visual analogue scale probably stands as a simple surrogate of the PEF. The oxygen saturation also increased in the sophrology group, by 1% on average, while no change occurred in the control group. This result was statistically significant, however, we need to admit that it is not clinically relevant.

average, while no change occurred in the control group. This result was statistically significant, however, we need to admit that it is not clinically relevant.

Sophrology focuses on breathing and body movements in the context of tension and relaxation. The asthma attack, from a sophrologist's point of view, represents a sudden physiological disorganization against which one can mentally and bodily interact. We may hypothesize that sophrology facilitates the relaxation of bronchial smooth muscles and the elimination of bronchial mucus. Added to the conventional therapy using corticosteroids and bronchodilators, sophrology might contribute to improve expiratory physiological capacities. As a result, the PEF increases, the feeling of dyspnea decreases, and the gas exchange ameliorates.

Unfortunately, the quality of life scores were not significantly higher in the sophrology group than in the control group, at the end of the hospitalization. Usually, patient reported outcomes require larger cohorts to be statistically modified, as reported in our previous quality of life studies. <sup>45</sup>

Unsurprisingly, we found no difference between the two groups in

terms of use or doses of conventional medical treatment, that is

oxygen, corticosteroids, and bronchodilators. Sophrology appears to be an interesting adjuvant therapy for asthma but we would not recommend using it as an "alternative" therapy. Indeed, the level of evidence of the effectiveness of pharmaceutical treatments for asthma is clear, and neither sophrology nor any other non-pharmaceutical therapy should claim to replace them. An Nevertheless, that does not forbid us to "look beyond the guidelines." In the adult asthma population, some interest has been recently shown for other non-pharmacologic therapies, such as pulmonary rehabilitation, focused breathing techniques, and bronchial thermoplasty, but these techniques are not fully adapted to children. Therefore, in the pediatric population, we suggest using sophrology as an adjuvant therapy to

# 4.1 | Study limitations

outcomes' assessment.

current guideline-based treatment for asthma.

Inherently, this type of study cannot be carried out with complete blindness, however the biases have been limited, as the physical therapists have not modified their usual practices during the clinical trial. Moreover, the sophrologists have not been involved in the

The results of this study apply to a population of hospitalized

children, where the severity of asthma and the level of stress are, by definition, expected to be high. It would therefore be interesting to evaluate sophrology in the outpatient population, during consultations, or therapeutic education sessions. Moreover, a high number of eligible children did not participate in the study because of logistic issues; indeed, our sophrologists were not only dedicated to the research, and many children were hospitalized during the weekends,

Finally, only one session of sophrology was performed during this study, whereas several sessions are usually necessary in actual practice. Therefore, we plan to conduct a study measuring the impact of a full sophrology program on the quality of life of children with chronic diseases.

### **5** | CONCLUSION

when the investigators were not available.

This randomized controlled clinical trial assessed, for the first time, the impact of sophrology on asthma in a cohort of 74 hospitalized children. When added to the conventional therapy, one session of sophrology significantly improved the peak expiratory flow, the oxygenation, and the feeling of dyspnea. This study shows the promise of sophrology as a new adjuvant therapy to current guideline-based treatment for asthma in the pediatric population. Further studies using a complete sophrology program among non-hospitalized children and measuring their quality of life, should be considered.

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#### **CONFLICTS OF INTEREST**

The authors declare no conflicts of interest.

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