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ORIGINAL RESEARCH

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Oral findings in pediatric patients with allergic rhinitis and asthma: a cohort study of an Italian setting

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Abstract

Allergic rhinitis and asthma are two frequent respiratory clinical entities commonly encountered in pediatric clinical settings. Previous studies have evaluated the influence of these two conditions on oral health, but conflicting results have been obtained. The present cohort study aimed to record oral findings (*i.e.*, caries, plaque, gingival inflammation and mouth breathing) in 50 pediatric patients diagnosed with allergic rhinitis and/or asthma in an Italian pediatric setting and to compare them to a control group of 50 healthy children. The following oral indexes were calculated: Periodontal Screening and Recording (PSR), Plaque Control Record (PCR), and Decayed Missing Filled Teeth (DMFT) Index. The absence or presence of mouth breathing was also recorded. Descriptive and inferential statistics were conducted. Statistically significant differences were found between cases and controls for PSR ($p = 0.0051$) and PCR scores ($p < 0.0001$), whereas no significant differences were detected for DMFT. Mouth breathing was found among 20 (40.00%) patients of the Case Group, while in the Control group only in 11 (22.00%) patients, and no significant differences were found between allergic rhinitis and asthma gradings for mouth breathers ($p > 0.05$). Finally, linear regressions showed a significant influence of PSR ($p = 0.0051$) and PCR ($p < 0.0001$) on the Case group. Mouth breathing also significantly influenced PCR scores of the Case group ($p = 0.0206$). Accordingly, allergic rhinitis and asthma can promote mouth breathing, plaque accumulation, and periodontal inflammation. Based on these considerations, pediatric dentists and physicians are expected to know the influence of respiratory conditions on oral health and consider this aspect when taking care of children.

Keywords

Allergic rhinitis; Asthma; Pediatric patients; Dental caries; Periodontal conditions; Plaque control record; Periodontal screening and recording; DMFT; Dentistry; Pediatrics

1. Introduction

Allergic rhinitis is a clinical entity defined by symptoms like sneezing, nasal pruritus, airflow obstruction and nasal discharge caused by mucosal inflammation due to immunoglobulins type E (IgE) response towards inhaled allergens like pollens, molds, pests, dust mites and pets [1].

Asthma is a worldwide chronic disease widespread, affecting about 300 million people. It causes respiratory symptoms such as wheezing, shortness of breath, chest tightness and cough with various degrees of time, frequency and intensity of occurrence [2]; however, it should be taken into consideration that the disease is often underdiagnosed or undertreated [3].

Regarding pediatric settings, the prevalence of allergic rhinitis (AR) was estimated to be between 0.8 to 14.9% in 6–7-year old patients and between 1.4 to 39.7% in 13–14-year old children all over the world [3]. According to the Centers for Disease Control, asthma prevalence was estimated to be 6.6% among children aged 5–14 years old [4]. Moreover, allergic rhinitis is believed to be strongly associated with asthma [5]. Genetic and familial predisposition, environmental factors, mother's habits and life exposure to home and external environment have been identified as risk factors [6].

Different studies assessed the prevalence and main characteristics of young asthmatic patients [7]. In this context, it is worth mentioning that associations between allergic rhinitis, asthma and oral findings have been widely investigated. In patients with allergic rhinitis, the typical symptom of nasal obstruction increases the total airway resistance and induces oral respiration, causing oral dryness. As regards asthma, the recourse to beta-2 agonists, which are used as therapeutic agents, affect salivary glands and decrease the salivary secretion and change the salivary components to increase dental caries activity. It induces oral dryness and results in an oral environment that is susceptible to various oral diseases affecting both teeth and soft tissues [8, 9].

A previous study showed that there are no significant differences in combined DMFT/dmft, salivary flow rate, buffer capacity of saliva, salivary levels of lactobacillus, and sugary food consumption between cases and controls, however higher salivary levels of mutans Streptococci have been found in allergic rhinitis patients [10]. According to Chuang and colleagues, the allergic rhinitis frequencies significantly correlated with caries frequencies in children suffering from this condition [11].

An observational comparative study conducted in Iran was conducted to examine the association between and DMFT, dmft and DMFS indices. The prevalence of dental caries resulted to be higher among patients with asthma than in the control group. Therefore, Authors concluded that having asthma could be considered a risk factor for the development of dental caries [12]. Additionally, it was showed that patients with asthma have significantly higher periodontal indexes, in particular probing depth (PB), plaque index (PI), gingival index (GI), and attachment loss (AL) [13, 14].

Additionally, current treatments (*e.g.*, inhaled drugs corticosteroids, beta2-agonists, and anticholinergics) have been related to an enhanced higher risk of caries, dental erosion, tooth loss, periodontal disease, and oral candidiasis, together with alterations in salivary components [15] and asthma was found to be a risk factor for increased periodontal inflammation and dental erosion [16]. Current evidence shows an association of asthma with mouth breathing [17], while no consensus has been reached for allergic rhinitis.

Therefore, present research aimed to record oral findings (caries, plaque, gingival inflammation and mouth breathing) in pediatric patients diagnosed with allergic rhinitis and/or asthma and to compare them to a control group of healthy children. The null hypothesis of the study is that no significant differences occur between the Case group and Control group regarding dental parameters and mouth breathing.

2. Materials and methods

2.1 Study design

This was a single-center parallel cohort study conducted in accordance with the Declaration of Helsinki (1964) and its later amendments and approved by the Unit Internal Review Board (2019-0904). The study followed STROBE guidelines for observational studies and was registered on clinicaltrials.gov (NCT05576142).

2.2 Setting

Pediatric patients diagnosed with allergic rhinitis and/or asthma at the Pediatric Clinic, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy were addressed for a dental examination at the Unit of Orthodontics and Pediatric Dentistry, Section of Dentistry, Department of Clinical, Surgical, Diagnostic and Pediatric Sciences, University of Pavia, Pavia, Italy. Healthy subjects were enrolled if negative to the eligibility criteria for allergic rhinitis and/or asthma. Enrollment started in September 2019 and ended in February 2021.

2.3 Participants

The inclusion criteria adopted were: age between 5 and 14 years old; the presence of allergic rhinitis diagnosed according to the Allergic Rhinitis for Asthma (ARIA) guidelines [1] and/or the presence of asthma diagnosed according to Global Initiative for Asthma (GINA) guidelines [13]. Instead, the following exclusion criteria were considered: refusal to participate in the study; the presence of systemic diseases that could alter oral conditions (Sjögren syndrome, celiac disease, calcium disorders).

2.4 Variables and measurements

Allergic rhinitis was defined "intermittent" for symptoms duration <4 days/week or <4 consecutive weeks, while for symptoms duration >4 days/week or >4 consecutive weeks, it was defined "persistent". The classification also provides the definitions of "mild" or "moderate/severe", respectively, for the absence or presence of: normal sleep; no impairment of daily activities, sport, leisure; normal work/school; no bothersome symptoms.

Gravity was recorded by combining both factors as follows: (1) mild intermittent; (2) mild persistent; (3) moderate-severe intermittent; (4) moderate-severe persistent. Therapy was also recorded, in particular, if patients were taking: oral antihistamines (OA), nasal antihistamines (NA), nasal steroids (NS) and specific immunotherapy (SI).

For asthma diagnosis, it was recorded if, in the previous 4 weeks from the visit, the patient had: daytime asthma symptoms more than twice/week; night waking due to asthma; reliever needed for asthma symptoms more than twice/week; activity limitations due to asthma. It was therefore recorded if asthma was: controlled (no symptoms); partially controlled (1–2 of the abovementioned symptoms); or uncontrolled (3–4 of the abovementioned symptoms) [18].

The type of asthma treatment was also recorded, in particular if patients were taking: inhaled corticosteroids (ICS), long-active beta agonists (LABA), leukotriene receptor antagonists (LTRA), and omalizumab (OMA).

A calibrated operator conducted an oral evaluation to assess the periodontal conditions, plaque accumulation and teeth status by means of a periodontal probe (UNC probe 15; Hu-Friedy, Chicago, IL, USA). The PSR index [19] was calculated to evaluate periodontal tissues with a score from 0 to 4 as follows: (0) absence of clinical signs; (1) bleeding on probing; (2) supra and/or subgingival calculus and/or defective margins; (3) periodontal pocket 4 mm to 5.5 mm deep with a colored band on probe partially visible; (4) periodontal pocket 6 mm deep with the colored band no longer visible. The PCR index [19] was adopted to assess plaque accumulation on the mesial, distal, vestibular and lingual sites of each tooth; and was calculated as a percentage of sites with presence of plaque on the total of sites. The DMFT Index [20] was chosen to evaluate teeth status recording the total number of teeth decayed, missing and with dental fillings or restorations.

The intraexaminer reliability was assessed by means of Intraclass Correlation Coefficient using PCR index. Ten random clinical cases were used to calibrate the operator, that had to assign PCR scores using clinical photographs; the

evaluation was repeated after seven days with a random order. Intraclass Correlation Coefficient was calculated and resulted to be excellent (ICC = 0.95).

The absence or presence of mouth breathing was also recorded according to Pacheco and colleagues' questionnaire by the presence of at least four characteristics in the visual assessment, by at least five positive answers of the questionnaire and by the positive result of two out of three breathing tests [21].

2.5 Study size

Sample size calculation (alpha = 0.05; power = 90%) for two independent study group and a continuous primary endpoint was performed concerning the primary outcome "DMFT". An expected mean of 1.24 with an expected mean difference of 0.92 and a standard deviation of 1.65 were hypothesized [22]; therefore, 50 patients per group were required.

2.6 Statistical methods

Statistical analysis was conducted with R Software (R version 3.1.3, R Development Core Team, R Foundation for Statistical Computing, Wien, Austria). For each variable descriptive statistics were calculated (mean, standard deviation, minimum, median, and maximum). For quantitative variables (PSR, PCR, DMFT, D, M, F), data normality of distributions was assessed with the Kolmogorov-Smirnov test. Subsequently, Student's t test was performed to compare the variables between Control and Case groups. χ^2 was performed to assess differences between therapeutic schemes for asthma and allergic rhinitis and for asthma symptoms. Linear regressions were performed to assess the influence of the following parameters on the oral indexes: rhinitis grading, asthma grading, mouth breathing, age, sex. Significance was predetermined for $p < 0.05$.

3. Results

One hundred patients fulfilling the inclusion criteria were recruited for the study and underwent clinical oral examination. The demographic data of the study sample are shown in Table 1. The mean age of the participants was 9.41 ± 2.3.

TABLE 1. Demographic characteristics of the study sample.

	Age (y)	
Demographic characteristics	Mean ± SD	Range
Male (n = 61)	9.59 ± 2.33	5–14
Female (n = 39)	9.13 ± 2.24	6–14

SD: standard deviation; y: years.

Among the Case group, 47 patients (94.00%) were diagnosed with allergic rhinitis and 23 (46.00%) with asthma. Table 2 shows the subdivision of patients according to allergic rhinitis grading and asthma control.

Table 3 presents the therapeutic regimens of patients and their relative allergic rhinitis grading. For grade 1, 6 (12.77%) patients were taking OA, while 10 (21.28%) the combination of OA and SI. Only 5 (10.64%) patients were taking OA + NS + SI. For grade 2, 11 (23.40%) patients were taking OA + NS. However, χ^2 revealed no statistically significant differences among the therapeutic schemes ($p > 0.05$).

Table 4 presents asthma symptoms related to its control. No significant differences were found among the possible combinations ($p > 0.05$).

In Table 5, therapeutic schemes for asthma grading of control are shown. Among the study sample, the majority of patients for each grade of control were taking ICS + LABA, but this is not significant ($p > 0.05$).

As regards oral indexes, statistically significant differences were found between Case and Control groups for PSR ($p = 0.0051$) and PCR scores ($p < 0.0001$). No significant differences were detected for DMFT, D, M, F indexes ($p > 0.05$) (Table 6).

Mouth breathing (Table 7) was found among 20 (40.00%) patients of the Case Group, while in the Control group only in 11 (22.00%) patients. No significant differences were found between allergic rhinitis and asthma gradings for mouth breathers ($p > 0.05$).

Linear regressions showed a significant influence of Case Group on PSR ($p = 0.0051$) and PI ($p < 0.0001$). Instead, no influence on DMFT index was recorded ($p = 0.83$). There was a significant mutual influence between asthma and allergic rhinitis gradings ($p = 0.0112$). Mouth breathing had a significant influence on PCR scores of the Case group ($p = 0.0206$), while the other rhinitis grading, asthma grading, and sex had no influence on the oral indexes calculated ($p > 0.05$). Age had a significant influence on PSR and DMFT indexes ($p < 0.05$) (Table 8).

4. Discussion

Allergic rhinitis and asthma are two frequent respiratory diseases in children that might occur together. This concept has been referred to in the literature as "united airway disease". Several studies have shown that most patients with asthma have concomitant rhinitis and the presence of this latter represents a risk factor for the development of asthma. Patients with asthma and rhinitis share common physiology, including bronchial hyperresponsiveness and higher reactivity to different stimuli. The immunopathology of allergic rhinitis is similar to the predominance of T-helper type 2 inflammation and tissue eosinophilia [23].

Previous studies have investigated the relationship between different respiratory diseases and oral pathological conditions, like asthma [24], rhinitis [9], and chronic obstructive pulmonary Disease (COPD) [25]. The primary oral condition investigated is represented by dental caries [8, 24, 26].

In a recent systematic review with meta-analysis by Moreira *et al*. [24], the association between asthma and oral conditions in children and adolescents has been investigated. The findings of this research highlighted that asthmatic children and adolescents had a higher Plaque Index than those without asthma. Therefore, the former is exposed to a higher risk of building up biofilm and developing tooth decay. Additionally, it was suggested that there are no differences between asthmatic and

TABLE 2. Number of patients diagnosed with allergic rhinitis and/or asthma according to the respective classifications; in brackets, number of patients presenting mouth breathing.

Rhinitis	Asthma				
No rhinitis	No asthma	Controlled	Partially controlled	Uncontrolled	Total
	0 (0.00)	2 (4.00)	1 (2.00)	0 (0.00)	3 (6.00)
1	16 (32.00)	6 (12.00)	1 (2.00)	2 (4.00)	24 (48.00)
2	8 (16.00)	6 (12.00)	3 (6.00)	0 (0.00)	17 (34.00)
3	1 (2.00)	0 (0.00)	1 (2.00)	0 (0.00)	2 (4.00)
4	3 (6.00)	1 (1.00)	0 (0.00)	0 (0.00)	4 (8.00)
Total	28 (56.00)	15 (30.00)	6 (12.00)	2 (4.00)	50 (100.00)

TABLE 3. Number of patients (and percentage) diagnosed with allergic rhinitis as regards grading and therapy.

Rhinitis		Patients under therapy (%)						
Grading	N (%)	No therapy	OA	NS	SI	OA + NS	OA + SI	OA + NS + SI
1	24 (51.06)	0 (0.00)	6 (12.77)	0 (0.00)	1 (2.13)	10 (21.28)	2 (4.26)	5 (10.64)
2	17 (36.17)	1 (2.13)	2 (4.26)	2 (4.26)	0 (0.00)	11 (23.40)	0 (0.00)	1 (2.13)
3	2 (4.26)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (2.13)	1 (2.13)	0 (0.00)
4	4 (8.51)	0 (0.00)	1 (2.13)	0 (0.00)	0 (0.00)	1 (2.13)	0 (0.00)	2 (4.26)
Total	47 (100.00)	1 (2.13)	9 (19.15)	2 (4.26)	1 (2.13)	24 (51.06)	3 (6.38)	8 (17.02)

OA: oral antihistamines; NS: nasal steroids; SI: specific immunotherapy.

TABLE 4. Number of patients (and percentage) diagnosed with asthma and relative grading. Columns represent the possible symptoms.

Grading	No symptoms	A	A + B	A + C	A + C+ D	A + B + C + D	Total
Controlled	15 (65.22)	0 (0.00)	0 (0.00)	0 (0.00)	1 (4.35)	0 (0.00)	15 (65.22)
Partially controlled	0 (0.00)	1 (4.35)	2 (8.70)	2 (8.70)	0 (0.00)	0 (0.00)	5 (21.74)
Uncontrolled	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (4.35)	1 (4.35)	2 (8.70)
Total	15 (65.22)	1 (4.35)	2 (8.70)	2 (8.70)	2 (8.70)	1 (4.35)	23 (100.00)

A: more than 2 episodes of asthma per week; B: nocturnal awakenings; C: more than two administrations per week of bronchodilators; D: limitation of normal activities.

TABLE 5. Number of patients (and percentage) diagnosed with asthma as regards grading and therapy.

Asthma		Patients under therapy (%)			
Grading	N	No therapy	ICS	OMA	ICS + LABA
Controlled	15 (54.55)	2 (9.09)	5 (22.73)	2 (9.09)	6 (27.27)
Partially controlled	5 (22.73)	0 (0.00)	0 (0.00)	0 (0.00)	5 (22.73)
Uncontrolled	2 (9.09)	0 (0.00)	0 (0.00)	0 (0.00)	2 (9.09)
Total	22 (100.00)	2 (9.09)	5 (22.73)	2 (9.09)	13 (59.09)

ICS: inhaled corticosteroids; OMA: omalizumab; LABA: long-active beta-agonists.

TABLE 6. Student *t* test comparisons for PSR, PCR, DMFT, D, M, F and T variables between control and case groups.

Variable	Groups	Mean	SD	Min	Median	Max	*p* value
PSR							
	Control	0.90	0.76	0.00	1.00	2.00	
	Case	1.34	0.77	0.00	2.00	2.00	$p = 0.0051$*
PCR							
	Control	37.00	23.00	10.00	30.00	80.00	
	Case	64.00	23.00	20.00	70.00	9.00	$p < 0.0001$*
DMFT							
	Control	1.40	2.07	0.00	0.00	7.00	
	Case	1.48	1.62	0.00	1.00	6.00	$p = 0.8300$
D							
	Control	0.80	1.55	0.00	0.00	5.00	
	Case	0.86	1.14	0.00	0.00	4.00	$p = 0.8262$
M							
	Control	0.00	0.00	0.00	0.00	0.00	
	Case	0.12	0.48	0.00	0.00	2.00	$p = 0.8010$
F							
	Control	0.60	1.28	0.00	0.00	7.00	
	Case	0.54	1.09	0.00	0.00	6.00	$p = 0.8012$

*SD: standard deviation; PSR: Periodontal Screening and Recording; PCR: Plaque Control Record; DMFT: Decayed Missing Filled Teeth. *: significance ($p < 0.05$).*

TABLE 7. Number of patients (and percentage) presenting mouth breathing according to the respective classifications of allergic rhinitis and/or asthma.

			Asthma		Case group	Control group
No rhinitis	No asthma	Controlled	Partially controlled	Uncontrolled	Total	
	0 (0.00)	1 (2.00)	1 (2.00)	0 (0.00)	2 (4.00)	
Rhinitis						
1	2 (4.00)	2 (4.00)	0 (0.00)	1 (2.00)	6 (12.00)	
2	3 (6.00)	3 (6.00)	2 (4.00)	0 (0.00)	8 (16.00)	
3	0 (0.00)	0 (0.00)	1 (2.00)	0 (0.00)	1 (2.00)	
4	3 (6.00)	0 (0.00)	0 (0.00)	0 (0.00)	3 (6.00)	
Total	8 (16.00)	6 (12.00)	4 (8.00)	1 (2.00)	20 (40.00)	11 (22.00)

TABLE 8. *p* values of linear regressions between allergic rhinitis grading, asthma grading, mouth breathing, age, sex and PSR, PCR and DMFT indexes.

	Dependent variables		
Independent variable	PSR	PCR	DMFT
Rhinitis grading	0.7680	0.7680	0.5025
Asthma grading	0.9492	0.9492	0.6951
Mouth breathing	0.2120	0.0206*	0.9280
Age	0.0406*	0.1500	0.0238*
Sex			
Male	0.9190	0.9854	0.3890
Female	0.8210	0.9379	0.4280

*PSR: Periodontal Screening and Recording; PCR: Plaque Control Record; DMFT: Decayed Missing Filled Teeth index. *: $p < 0.05$.*

non-asthmatic children and adolescents regarding gingivitis, developmental defects of enamel, or erosive tooth wear. It should be noticed, however, that the certainty of the evidence of this systematic review with meta-analysis was classified as "very low".

The present observational cohort study aimed to record oral findings (*i.e.*, caries, plaque, gingival inflammation, and mouth breathing) in pediatric patients diagnosed with allergic rhinitis and/or asthma and to compare them to a control group of healthy children. The null hypothesis of the study was that no significant differences occurred between the Case group and Control group as regards dental parameters and mouth breathing. This null hypothesis has been partially rejected since there was a significant difference between the study and control group regarding some of the clinical parameters assessed.

In the study by Ho *et al*. [26], the Authors stated that the association between asthma, allergic rhinitis, and oral diseases remains inconclusive in adults. According to their results, allergic rhinitis, rather than asthma, might be associated with dental caries, periodontitis, and other oral diseases. Although their results partially agree with those obtained in the current study, no direct comparison can be made considering the different ages of the participants recruited in the two studies.

As to pediatric patients, a case-control study was conducted to assess the impact of inhaler use on dental caries [27]. According to the study results, inhaled drugs do not increase the prevalence of dental caries in pediatric asthma patients. However, there is a direct relationship between treatment duration and the prevalence of dental caries. In another study performed in Taiwan, children receiving asthma medications had had a higher prevalence of dental caries and a higher rate of severe caries than children without asthma [28]. Based on these considerations, it is quite difficult to understand whether the increased caries risk should be attributed to the respiratory conditions alone, to the medications, or both. In fact, as in our study, the majority of patients suffering from these diseases are submitted to a therapeutic protocol. Anyway, the results obtained in the current study are generally in accordance with previous research. For instance, Godara *et al*. [29] and Bahrololoomi *et al*. [30], also found no significant differences between asthmatic patients using inhalers and healthy subjects. Conversely, other Authors found a higher DMFT index in asthmatic patients, but such differences may be because dental caries is a multifactorial infectious disease depending on environmental, sociodemographic, behavioral, microbiological and nutritional factors [16, 27, 31]. As regards allergic rhinitis, our results agree with those of Bakhshaee *et al*. [32], who found no significant difference in the rate of tooth decay or DMF between participants with or without allergic rhinitis.

Despite no significant influence on DMFT index, the current study reported a significant increase in PCR (Plaque Control Record) and PSR (Periodontal Screening and Recording) in patients with respiratory diseases with respect to controls. Our results agree with previous research demonstrating a major plaque accumulation and gingival inflammation in children with respiratory diseases; however, these results are to be confirmed by further studies, as current evidence provided by systematic reviews is still very low [33]. In the present research, it was also found that children with allergic rhinitis and asthma have a major tendency to present mouth breathing which could be explained, respectively, by the obstruction of the airways and their increased resistance. The tendency to breathe exclusively through the mouth is linked to a reduction of the salivary rate, this latter likely enhanced by the pharmacological therapy, with a subsequently increased plaque build-up and gingival inflammation, as reported in previous research [17, 34]. In general, preventative strategies should be implemented for this kind of patients as susceptible of poorer oral hygiene [35].

The main limitation of this study is represented by its observational design. Moreover, considering children under a therapeutic protocol can represent a bias since drugs, besides the respiratory conditions, can influence on the parameters assessed, and this influence could differ based on the specific therapeutic agent. Therefore, future randomized clinical trials should be designed in order to understand better the influence of asthma and allergic rhinitis on oral conditions as well as to determine whether drugs could also influence on these parameters and, subsequently, to determine which therapeutic approach could be more favorable to avoid caries and periodontal disease in children. Another limitation of the study could be the only use of DMFT index to evaluate dental tissues, as it happened for recent studies [36, 37]. Future studies could consider adopting additional indexes for the detailed stadiation of hard tissues lesions, such as the International Caries Detection and Assessment System (ICDAS) and the evaluation of caries progression in pulpal and surrounding tissues with Caries Assessment Spectrum and Treatment (CAST), so that a general overview on teeth status can be performed.

5. Conclusions

Allergic rhinitis and asthma represent two frequent respiratory diseases in the pediatric population. Despite no significant influence on dental caries, the two conditions can promote higher values of PCR and PSR. Mouth breathing resulted to be influential on PCR.

AVAILABILITY OF DATA AND MATERIALS

Data are available upon request to the corresponding author.

AUTHOR CONTRIBUTIONS

MCV, AL, GLM, AS—designed the research study; MC—performed the research; analyzed the data; MP and SG—wrote the manuscript. All Authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

All procedures performed in this study were in accordance with the Declaration of Helsinki (1964) and its later amendments, and it was approved by the Unit Internal Review Board (2019-0904). The study was registered on clinicaltrials.gov

(NCT05576142).

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CONFLICT OF INTEREST

The authors declare no conflict of interest. Simone Gallo, Maurizio Pascadopoli and Andrea Scribante are serving as the Editorial Board members of this journal. We declare that Simone Gallo, Maurizio Pascadopoli and Andrea Scribante had no involvement in the peer review of this article and have no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to FSS.

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