

Comparability of asthma control test scores between self and physician-administered test

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ABSTRACT

Background: The Asthma Control Test (ACT) is a tool that allows physicians to estimate the control of asthma symptoms on each patient in a quick way.

Methods: We conducted a prospective single-center observational study enrolling 97 patients with asthma, selected from the Outpatient Respiratory Service of "Policlinico-Vittorio Emanuele" in Catania. Patients answered the ACT in full autonomy. Subsequently, the physician, blinded to the previous ACT evaluation, administered a new ACT and then assessed patients' medical condition during his/her visit. A second physician evaluated patients' level of symptom control according to GINA guidelines. Agreement in ACT score was analyzed using the Kendall coefficient of concordance (W) for ACT individual items and overall score. The impact of different education levels on the ACT was analyzed with the Mann-Whitney test.

Main findings: There was no significant difference in ACT total score obtained by either administration mode ($p > 0.05$). Responses to ACT single items showed a statistically significant difference between patients with lower and higher education levels in ACT items n°3 and 5, ($p < 0.05$), with lower education levels influencing patients symptom perception and disease control.

Moreover, a significant difference in the evaluation of asthma control was found between ACT and GINA assessment of symptom control ($p < 0.05$).

Purpose: There is no available information on whether there is a difference in the ACT questionnaire results when it is performed by the physician or the patient. This study aimed to evaluate a potential difference in reporting the level of control from patient self-administered ACT compared to physician-administered test.

1. Introduction

In the last decade, GINA international asthma guidelines [1] have mainly focused on the importance of long-term management of asthma, with the major goal of achieving and maintaining control of the disease symptoms. Asthma is defined as "controlled" when lung function assessment is improved and all manifestations of the disease are reduced

in intensity and frequency, preventing acute symptoms and the risk of future exacerbations, reducing the daily use of as-needed therapy and, as a result, minimizing the potential undesirable effects of rescue therapies such as systemic corticosteroids [2,3].

It is also well established that failure to achieve control is related to the future risk of exacerbations, emergency room visits, hospitalizations, a decrease in lung function, deterioration in quality of life and increases in health costs [4,5]. Several tests [6,7] have been validated to assign an objective and repeatable numerical score to assess the level of asthma control, but the most widely used tool is the Asthma Control Test (ACT) validated in 2004 by Nathan et al. [8].

The ACT is a simple 5-question questionnaire that provides a quick estimate of the patient's symptoms control, with ACT score >19

Abbreviations: ACT, Asthma Control Test; GINA, Global Initiative for Asthma; MDI, metered dose inhaler.

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indicating well-controlled asthma, 16–19 partially controlled asthma, and 5–15 very-poorly controlled asthma. This tool allows physicians to evaluate the smallest changes in the score (a difference of 3 points is considered clinically significant) that reflect the variations of asthma control and therefore, to evaluate the effectiveness of interventions and to personalize the treatment maintenance and adjustment for each patient [9–11]. Nevertheless, several studies [12–14] suggested that many asthmatic patients often remain undertreated without adequate disease control, despite the existence of guidelines for the management of asthma treatment, and this is probably because of patients' poor perception of their symptoms. Although it is possible to attribute a numerical ACT value to the level of asthma control, this does not always reflect the patients' real perception of his/her symptoms [8,15].

Few published studies have focused on the patients' real asthma perception [16,17]. It is well known that many asthmatic patients have a higher threshold for detecting increased resistive loads compared to normal subjects, suggesting that the sensitivity to the recognition of changes in airways resistance might be decreased due to the chronic presence of airflow obstruction even without showing no symptoms [15, 18]. Furthermore, patients sometimes understand and use the word "control" differently from healthcare staff, for example, based on how fast their symptoms relieve with the use of the emergency drugs and what they perceive in terms of control differs from what clinically and instrumentally is evaluated by the physician during his consultation [19]. Therefore, the concept of symptoms' perception is fundamental, since it often influences the real meaning of disease control, and it determines adjustments to medication regimes and sometimes disease self-management by patients [20,21]. There are no studies that investigate the comparability between self-administered and physician-administered ACT. Therefore, this study seeks to answer the following research questions:

- 1) Evaluate the possible difference between the level of control resulting from patients' self-administered ACT compared to the physicians-administered test.
- 2) Evaluate any differences between the two test administration methods for each question.
- 3) Evaluate the difference between patients' self- and physicians-administered ACT in relation to patients' level of education.
- 4) Evaluate the possible difference between the two modes of ACT administration (interview versus self-administration) with the physician's judgment of asthma control according to GINA guidelines.

2. Materials and methods

2.1. Study design

This is a prospective single-center observational study. The study is under the agreements of the Helsinki Declaration and was approved by the "Catania1" ethics committee of the Azienda Ospedaliero-Universitaria "Policlinico Vittorio Emanuele", Catania (protocol number No. 204/2018/PO).

2.2. Study participants

Participants were recruited from the Outpatient Service of Respiratory Unit - A.O.U. "Policlinico-Vittorio Emanuele" in Catania between September 1, 2018, and July 31, 2019. Adult patients aged at least 18 years old with a diagnosis of asthma according to GINA criteria 2018 were screened for participation and eventually recruited. All the potential participants had been under asthma treatment for at least three months from the diagnosis and scheduled for their first follow-up visit. Patients with any associated pulmonary diseases that may mimic asthma such as chronic obstructive pulmonary disease, bronchiectasis, bronchopulmonary aspergillosis, lung cancer were excluded.

The demographic characteristics (age and sex) and the basic features

of bronchial asthma (severity of asthma according to GINA guidelines 2018, sensitization to allergens, lung function in terms of FEV₁ and FEV₁/FVC%, exacerbations, maintenance therapy, FeNO and eosinophilia) were evaluated for each patient and recorded into a database.

All patients were receiving pharmacological treatment according to GINA guidelines.

Adherence to ongoing inhalation therapy, the eventual use of systemic corticosteroids, anti-leukotrienes, use of biological drugs (omalizumab and mepolizumab) was recorded, as well as participants' level of education.

Patients gave their written informed consent to participate before they received an ACT questionnaire to fill out for self-administration ahead of the physician's consultation.

2.3. Measurements: asthma control test (ACT)

The ACT consists of five items: (1) activity limitation, (2) shortness of breath, (3) awaking because of asthma symptoms, (4) use of reliever medication and (5) global judgment of asthma control. All items refer to the last 4 weeks and are scaled from 1 to 5. The sum indicates asthma control with scores of 25 meaning perfectly controlled asthma, scores >19 indicating well-controlled disease, scores between 15 and 19 reflecting partially controlled and scores <15 poorly controlled asthma, respectively [10]. Reliability was estimated, ranging from 0.77 to 0.85 [10]. A minimally clinically important difference of 3 points for change over time was identified [11].

2.4. Measurements: GINA multidimensional assessment of symptom control

GINA guidelines use four questions concerning diurnal and nocturnal symptoms, activity limitation, and rescue medication to define the level of asthma control (controlled, partly controlled and uncontrolled). When three or more items of the questions are present in any of the past 4 weeks asthma is considered uncontrolled.

2.5. Modes of ACT administration and data collection

All the participants signed their consent and were provided with an ACT sheet to fill on their own, before the visit. Patients answered the questionnaire in full autonomy and, in the end, put their questionnaire in a sealed envelope; moreover, patients were asked not to inform the physicians about their estimated ACT scores. Subsequently, the physician (blinded to the previous ACT evaluation) administered a new ACT questionnaire, by explaining each question item to patients and inserting his evaluation sheet in a sealed envelope to assess patients' medical condition during his/her visit. A second physician evaluated the patient and assessed his/her asthma severity and level of symptom control according to GINA guidelines. The two physicians (SG, GC), independently examined the patients, assessed their level of asthma symptoms control with ACT and GINA questions, respectively. All three assessments were performed at the same outpatient visit. Physicians (SG, GC) were the same during the entire study period.

2.6. Statistical analysis

Descriptive statistics for the study population is presented as mean values and standard deviation (SD) for continuous variables, median and interquartile range (IRQ) for non-normally distributed variables and numbers and percentages for categorical variables.

The normality of data distribution was checked using the Kolmogorov–Smirnov test. To assess the agreement in ACT scores between patient-administered and physician-administered questionnaires, interrater reliability was analyzed using the Kendall coefficient of concordance (W) for ACT individual items and overall score, with $p < 0.05$ deemed significant. Patients were categorized into two classes based on

the level of education achieved: 1) elementary and lower middle school; 2) upper secondary school and degree. The impact of different education levels on the ACT was tested with the Mann-Whitney test.

Patient- and physician-administered ACT questionnaires were compared using the Wilcoxon signed-rank test.

Wilcoxon signed-rank test was also used to compare the GINA assessment with the ACT self- and physician-administered, (all of each variable was classified in 3 levels: Poor, partial and well control).

Data were analyzed using SPSS version 18 software (SPSS Inc., Chicago, IL, USA).

A P-value of <0.05 was considered statistically significant.

3. Results

3.1. Main characteristics of the participants

The sample consisted of $n = 97$ patients (59% female) with a median age of 56 (IQR 14) years. Mean FEV1 percent predicted was 79 (SD 21). Table 1 shows patient demographics and clinical findings.

3.2. Impact of mode of administration on ACT assessment

The median total ACT score was 18 (IQR 9) for both physician-assisted administration and patient-only administration, as shown in Fig. 1.

There was no significant difference in ACT total score obtained by either administration mode ($p > 0.05$), Fig. 1.

W coefficient of agreement between ACTs administered by the physician and by patients alone was high for all the items (Q1: 0.91; Q2: 0.89; Q3: 0.88; Q4: 0.88; Q5: 0.88; ACT: 0.94; $p < 0.001$).

Nevertheless, the median ACT point assigned to question 4, was significantly different ($p < 0.02$) between patient self-administered [4 (IQR 2)] and physician-administered ACT [5 (IQR 2)] as shown in Fig. 2.

When comparing total ACT score between self and physician-

Table 1

Clinical and demographic characteristics of the studied population.

Baseline demographic and clinical characteristics of patients	
Total population examined	97
Age (y), median (IQR)	56 (14)
Sex, n (%)	
Men	40 (41%)
Women	57 (59%)
GINA Class, n (%)	
GINA 1-2	17 (17%)
GINA 3-4	20 (21%)
GINA 5	60 (62%)
Positive skin prick test, n (%)	75 (77%)
ICS plus LABA, n (%)	93 (96%)
LAMA, n (%)	45 (46%)
OCS, n (%)	9 (9%)
Anti-leukotrienes, n (%)	11 (11%)
Biologic Therapy (Omalizumab/mepolizumab), n (%)	23 (24%)
ACT score, median (IQR) patient-administered	18(9)
ACT score, median (IQR) physician-administered	18(9)
FEV1, mean % (SD)	79 ± 21
FVC, mean % (SD)	94 ± 18
FEV1/FVC%, mean % (SD)	68 ± 15
FeNO, median (IQR)	35 (41)
Eosinophils (U/mmc), mean (SD)	382 ± 366
Asthma exacerbations/Year, mean (SD)	3 (4)
Education, n (%)	
Low level of education	42 (43%)
High level of education	55 (57%)

Abbreviations: GINA: Global Initiative for Asthma; ICS: inhaled corticosteroids; LABA: long acting beta agonists; LAMA: long acting muscarinic antagonists; OCS: oral corticosteroids; ACT: asthma control test; FEV₁: forced expiratory volume at the first second; FVC: forced vital capacity; FeNO: fraction exhaled nitric oxide; SD: standard deviation; IQR: interquartile range.

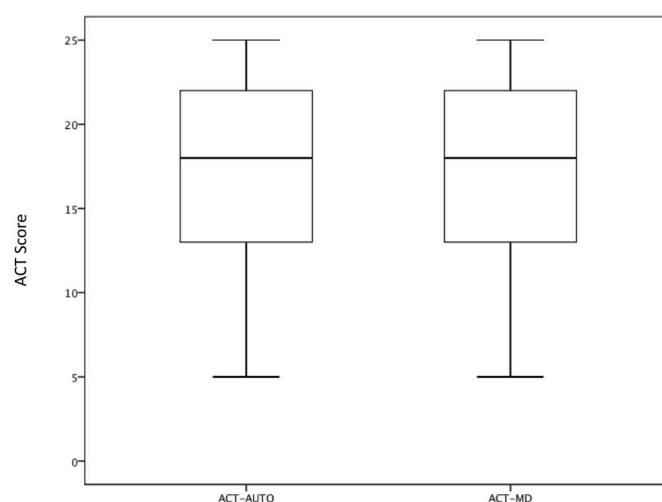


Fig. 1. Difference in ACT total score between patient self- and physician-administered questionnaire.

Each box plot represents median and the 25th and 75th percentiles.

The horizontal line indicates the median value (50th percentile), while the box contains the 25th to 75th percentiles of dataset. The black whiskers mark the 5th and 95th percentiles.

ACT: asthma control test.

ACT-AUTO: self-administered ACT.

ACT-MD: physician-administered ACT.

MD: physician.

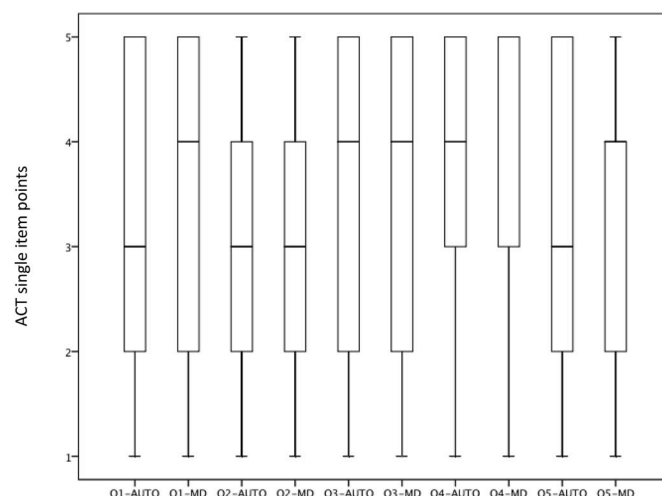


Fig. 2. Single item ACT points comparison between patient self- and physician-administered questionnaire.

Each box plot represents median and the 25th and 75th percentiles.

The horizontal line indicates the median value (50th percentile), while the box contains the 25th to 75th percentiles of dataset. The black whiskers mark the 5th and 95th percentiles.

ACT: asthma control test.

ACT-AUTO: self-administered ACT.

ACT-MD: physician-administered ACT.

MD: physician.

administered questionnaires, according to the educational level groups (Low vs. High), there was a mean difference in ACT score of -1.24 (SD 3.8) and 0.27 (SD 2.2) for low and high education level respectively ($p = 0.04$). The negative value of the mean difference indicates that patients with lower education level had a worse perception of their asthma control when filling out the questionnaire by themselves compared to physician-assisted administration.

No mean difference, according to educational level, was found in the points assigned for each single ACT item, except for items 3 and 5 ($p = 0.03$, $p = 0.01$ respectively), as shown in Fig. 3.

Moreover, a significant difference in the evaluation of asthma control (uncontrolled/partially-controlled/well-controlled) was found between patients- and physicians-administered ACT score and the level of asthma control assigned using the GINA questions (GINA multidimensional assessment of symptom control) to identify asthma control, (ACT-AUTO vs. GINA $p = 0.026$, ACT-MD vs. GINA $p = 0.004$). Apparently, GINA assessment tends to overestimate asthma control as compare to ACT, as shown in Fig. 4.

4. Discussion

To the best of our knowledge, this is the first study to examine and compare patients' and physicians' perceptions of asthma control, simultaneously using the ACT questionnaire. Several published studies [23–25] have shown a certain grade of mismatch between patients' and clinicians' assessment of their asthma control.

Matsunaga and coworkers [23] showed that the subjective perception of the physicians did not show a good concordance with patients' asthma control evaluated with the 5-items Asthma Control Questionnaire (ACQ). Crespo-Lessmann et al. [24] showed that there is a grade of discordance of about 27% between patients and physicians symptomatic control of patients with moderate-to-severe asthma, with physician overestimating.

A study from the UK [25] reported that both patients and health care professionals' subjective evaluation of asthma control tend to overestimate compared to the objective score obtained by ACT.

The ACT was originally designed to be self-administered, although it may also be completed through a physician's interview. Although it has been widely used in clinical studies and clinical practice, to the best of our knowledge, no published studies compared the different formats for administering this questionnaire to asthmatic patients.

The results of our study demonstrate that both self-administration and physician-assisted administration ACT are valid approaches for evaluating patients' asthma control and lead to a similar final score, with a good overall agreement.

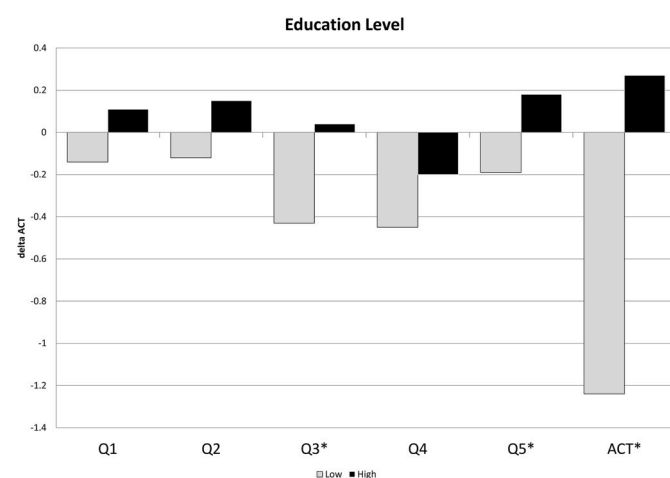


Fig. 3. Concordance between patient self- and physician-administered ACT and relationship with patients' education.

Each box represents the mean delta ACT score for each question between patient and physician rank.

ACT: asthma control test.

ACT-AUTO: self-administered ACT.

ACT-MD: physician-administered ACT.

MD: physician.

Low: low education level.

High: high education level.

Nevertheless, despite the good agreement between self- and physicians-administered total ACT scores, we found differences when comparing the points assigned to each item of the questionnaire.

In particular, we found a statistically significant difference in the fourth item concerning patients' opinions about the use of rescue medication (inhaler or nebulizer) in the last 4 weeks. We found a difference in score obtained from self-reporting as compare to the rating acquired through physician interviews (median self-administered ACT 4 (IQR 2) vs. median physicians-administered ACT 5 (IQR 2)).

These results suggest that some patients overestimate the frequency with which they use rescue medication; this may be due to many reasons. One of these reasons is cultural. Sometimes, patients do not like to use rescue medication because they are culturally predisposed to the theory that they will become "dependent" on that medication. Therefore, after using rescue medication once or twice, they already feel they have used it many times.

However, before making a wrong judgment, it is also necessary to determine if patients that overestimate the use of rescue medication are using their inhalers properly and still have enough doses inside the metered-dose inhaler (MDI). This is because up to 40% of patients [22] believe they are taking their asthma medication when they actually are activating an empty or nearly empty MDI, which will not have any effect. In that case, patients are underestimating their asthma control with overuse of inhaler regardless they are using it correctly or whether they are using an empty or nearly empty device.

We found a mean difference in ACT score between self- and physician-administered questionnaires when comparing the patients according to the educational level groups. Our results showed that patients with a lower education level had a worse perception of their disease's control when filling out the questionnaire by themselves as compared to physician-assisted administration.

Conversely, patients with higher education were more likely to self-evaluate their asthma control with the same accuracy of the physician-administered questionnaire.

These findings may raise the issue as to whether this difference in the method of administration of the ACT questionnaire affects the reporting of asthma control data, and more importantly, the final asthma clinical assessment.

This is in keeping with previous studies showing a relationship between asthma knowledge and patients' education, with a higher education level associated with more knowledge of their disease [26–28]. This is probably because patients with less education may not fully understand the information given by health-care providers. For the same reason, we can speculate that patients with a lower level of education have a reduced perception of their asthma control. This is a very important aspect to consider because it may influence patients' asthma self-management and quality of life.

Indeed, misinterpretation of ACT items might be due to patients' understanding of the questions but also to the presence of symptoms related to other comorbidities that might act as confounding factors [29].

Moreover, it has already been shown that patients' education may affect the results of quality of life (QoL) questionnaires in asthmatic patients [11,30–32].

Bearing in mind that clinical assessment remains the cornerstone of asthma management, this finding may hopefully contribute to implementing educational programs for patients with asthma, especially in individuals with a lower level of education, not only focused on training on inhaler techniques but also directed to a better understanding of their symptoms' perception [22].

We can also speculate that ACT can be spread in the waiting rooms of general practitioners or in the pharmacies for patients' self-testing and it might be useful in the detection of unrecognized uncontrolled patients.

Furthermore, our results should encourage physicians to better explore patients' perspectives in terms of asthma symptoms' perception and control during their complete assessment.

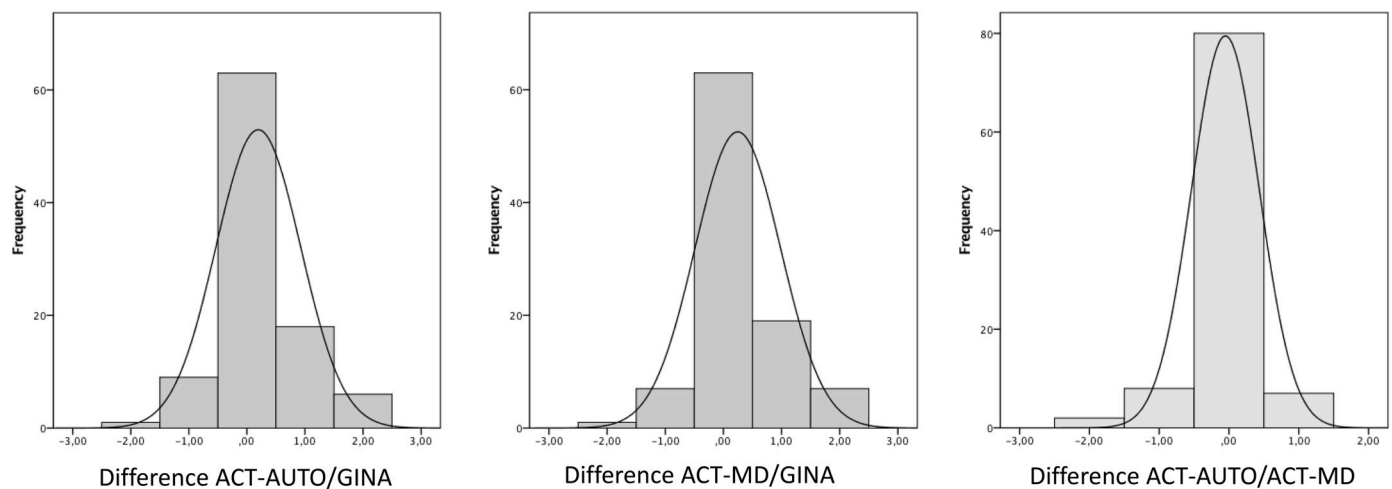


Fig. 4. Difference between patient self- or physician-administered ACT and GINA control score.

Frequency histogram of asthma control score difference between GINA assessment of symptom control and patient self- or physician-administered ACT and between physician-assisted and patient auto-filled ACT questionnaire. The solid line represents normal distribution.

ACT: asthma control test.

GINA: Global Initiative for asthma.

ACT-AUTO: patient self-administered ACT.

ACT-MD: physician-administered ACT.

Finally, our study confirmed previously published results [33,34] that showed there is a minor discrepancy between ACT score and GINA-defined asthma control, with a tendency of GINA method in overestimating disease control; which is probably due to different approaches of the two tools in taking into account asthma manifestations.

4.1. Strengths and limitations

The main strength of the present study is the use of the same instrument (ACT) administered by a physician interviewer or filled out by patients themselves

Exploring the same domains in assessing patients' symptoms and daily functioning, thus allowing effective comparisons between perceptions of the entire range of items considered important in defining asthma control.

However, it is to note that this study was conducted in a single-center, therefore the results may not be generalized.

Further research should focus on how the perception gaps between patients and doctors could be decreased.

5. Conclusions

This study shows that there is a significant gap between the perception of different domains of control in patients with asthma and the understanding that the doctors caring for asthma patients have about their patients' perceptions. This is particularly important in the areas of asthma control, because it may affect the pharmacological treatment, management plans and patients' quality of life. Physicians should be very careful in evaluating patients' perception and understanding of their disease control, especially in patients with a lower level of education, to foster a good patient-doctor relationship that may influence asthma control and management.

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CRediT authorship contribution statement

Claudia Crimi: Conceptualization, Methodology, Writing - original draft, Writing - review & editing. **Raffaele Campisi:** Writing - original draft, Writing - review & editing, Supervision. **Alberto Noto:** Conceptualization, Methodology, Data curation, Formal analysis, Writing - original draft. **Sabrina Genco:** Investigation, Data curation, Writing - original draft. **Giulia Cacopardo:** Investigation, Data curation, Writing - original draft. **Santi Nolasco:** Investigation, Data curation, Validation. **Nunzio Crimi:** Conceptualization, Writing - review & editing, Supervision.

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