





Ischemia-modified albumin as a marker of disease severity and hospitalization in community-acquired pneumonia: a prospective case-control study

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ABSTRACT

Aims: Community-acquired pneumonia (CAP) is an important public health problem because of its high morbidity, mortality, and health care costs. Many biomarkers have been used to determine the severity and prognosis of pneumonia. Ischemia-modified albumin (IMA) is a marker of oxidative stress and has been found to increase in many inflammatory conditions. The aim of this study was to investigate the role of IMA levels in CAP and to evaluate their relationship with pneumonia severity.

Methods: A total of 150 patients with a diagnosis of CAP and 150 healthy individuals were included in the study. IMA levels were evaluated in both groups. The patients with CAP were divided into outpatient, inpatient and intensive care groups, and their IMA levels were compared.

Results: There was no significant difference between the two groups in terms of age or gender ($p > 0.05$ for both). No significant difference was observed in the IMA levels of the patient and control groups ($p > 0.05$). The lowest IMA level was observed in the outpatient group ($p = 0.001$). When the patients in the outpatient and hospitalized (inpatient and intensive care together) groups were evaluated, the cut-off value of IMA was 77.60 ABSU, sensitivity was 64.9%, specificity was 75.0%, positive predictive value was 89.2%, and negative predictive value was 40.3%.

Conclusion: IMA does not appear to differentiate CAP patients from healthy individuals; however, it may be useful in reflecting disease severity and supporting hospitalization decisions.

Keywords: Oxidative stress, biomarker, hospitalization decision, inflammation, risk stratification

INTRODUCTION

Pneumonia is responsible for a significant portion of doctor consultations, treatment costs, missed work and school days, and deaths worldwide.¹ It is the most common cause of infection-related deaths. The reported annual incidence of pneumonia in Europe is 0.5-1.1%, which increases with age.^{2,3} While deaths due to infectious diseases have decreased with the widespread use of antibiotics and active immunization as a result of the great advances in medicine, community-acquired pneumonia (CAP) still leads to high rates of morbidity and mortality. In Turkey, lower respiratory tract infections constitute the fifth cause of death at a rate of 4.2%.⁴

Due to their localization, the lungs are exposed to many toxic, irritant and infectious agents. In case of infection caused by the entry of microorganisms into the body, there is a significant increase in the production of free radicals.⁵ A change in the balance between oxidants and antioxidants is defined as oxidative stress, which has been associated with various respiratory tract diseases. Asthma, chronic obstructive pulmonary disease (COPD), and bronchiectasis have been shown to be associated with oxidative stress.^{6,7}

In cases of pneumonia, there are several inflammatory biological markers used for the prediction of disease severity and treatment follow-up.⁸ Moreover, various objective criteria have been defined to help the physician make treatment decisions in hospitalized patients. In such cases, the pneumonia severity index (PSI) is the most commonly used tool to select an appropriate empirical antibiotic and determine disease severity in patients with pneumonia.

Among all the recently studied cardiac markers, ischemia-modified albumin (IMA) is the test approved by the U.S. Food and Drug Administration.⁹ The principle of this test is the reduction of cobalt-binding capacity of albumin by oxidative free radicals generated during hypoxic acidosis through chemical changes in albumin. This new albumin molecule is called IMA and measured spectrophotometrically using the albumin cobalt binding (ACB) test.^{10,11} The formation of this new albumin molecule that has lost its ability to bind cobalt is one of the earliest markers of ischemia.¹² Recent studies have shown that IMA, which attract researchers' interest as a cardiac ischemia marker, can also increase in different

pathologies.¹³⁻¹⁵ IMA is generated due to high oxidative stress not only in myocardial ischemia but also in different ischemia models affecting other organs.¹⁶ Serum IMA levels increase in non-cardiac ischemic diseases, pulmonary embolism, cardiopulmonary resuscitation, end-stage renal diseases, cerebrovascular ischemia, acute mesenteric ischemia, systemic sclerosis, arthroscopic knee surgery, postexercise skeletal muscle ischemia, diabetes mellitus, liver diseases, various cancers, infection, and peripheral arterial diseases.^{10,16}

In today's conditions where we are confronted with oxidative stress at any moment, there are not sufficient studies evaluating the relationship between pneumonia and oxidative stress. There is a study in the literature that was conducted in the emergency department, which reported that IMA was associated with pneumonia, but no comprehensive study has been undertaken to further investigate the relationship of this oxidative stress marker with pneumonia severity and etiopathogenesis. The aim of this study was to investigate the role of the IMA level in CAP and to evaluate its relationship with pneumonia severity.

METHODS

Ethics

This study was approved by the Clinical Researches Ethics Committee of Ankara Yıldırım Beyazıt University (Date: 02.04. 2018, Decision No: 73). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki. Written informed consent was obtained from all individual participants prior to their inclusion in the study.

This single-center, prospective, case-control study was conducted in the Department of Chest Diseases between April 2018-March 2019.

A total of 150 adult patients newly diagnosed with CAP and 150 healthy controls were included in the study. The controls were randomly selected from healthy individuals who attended routine controls in the outpatient clinic and had no known acute infection at the time of enrollment. However, detailed screening for chronic diseases and inflammatory conditions was not systematically performed. In the subgroup analysis, the patients with CAP were divided into three groups according to PSI: those that received outpatient treatment (outpatient group), those admitted to the hospital (inpatient group), and those admitted to the intensive care unit (intensive care group). The PSI classification was used to assess disease severity and to guide hospitalization decisions, with higher PSI classes indicating more severe disease and a greater likelihood of inpatient or intensive care admission. Patients were classified according to PSI risk classes (I-V), where higher classes indicate increased severity and a higher likelihood of hospitalization or intensive care admission. The demographic data, clinical and laboratory parameters of all the CAP groups and the healthy controls were recorded. The IMA and C-reactive protein (CRP) levels were also evaluated in the CAP and control groups and compared between the three CAP subgroups. In addition, the correlations between the IMA and (CRP) levels were assessed among the patients

with CAP. Patients or controls aged below 18 years, those with mental disorders, and pregnant women were excluded from the study.

Laboratory Tests

IMA measurement was performed using the reduced ACB capacity test with the rapid and colorimetric method developed by Bar-Or et al.¹⁷ To summarize, 200 μ L patient serum was transferred to glass tubes, to which 50 μ L 0.1% $\text{CoCl}_2 \cdot 6\text{H}_2\text{O}$ (Sigma Aldrich Lot: S38901-248; Sigma Aldrich, St. Louis, MO, USA) was added. After shaking gently, the mixture was incubated for 10 minutes to ensure sufficient cobalt-albumin binding. Then, 50 μ L 1.5 mg/ml dithiothreitol (DTT) (Sigma-Aldrich Lot: D5545-1G; Sigma-Aldrich) was added as the coloring agent. After 2 minutes, to stop the binding between cobalt and albumin, 1 mL 0.9% NaCl was added. A blank was prepared for each sample. At the DTT addition step, to obtain a blank, 50 μ L distilled water was used instead of 50 μ L 1.5 mg/ml DTT. Absorbance values at 470 nm were measured using a spectrophotometer and recorded. Color development in the samples with DTT was compared with the tubes containing the blank solution, and the results were presented as absorbance units (ABSU).

CRP levels were measured turbidimetrically using a BNII Nephelometer Analyzer (Siemens, Munich, Germany) with the CardioPhase hsCRP kit (Siemens Healthcare Diagnostics Products, Marburg, Germany).

Statistical Analysis

The data was performed using IBM® SPSS® (ver. 20.0; SPSS Inc., Chicago, IL, USA) software package. The normality distribution of data was evaluated using the Kolmogorov-Smirnov test. Parametric tests were applied for variables with normal distribution. Mean \pm standard deviation were used in the descriptive statistics of continuous variables. Pearson's test was used for correlation analysis. In the intergroup comparisons of categorical variables, the chi-square and Fisher's exact tests were used. When comparing two groups in relation to continuous variables, Student's t-test was conducted. Analysis of variance was used. Tukey's test was employed as a post hoc method. Non-parametric tests were not applied as the data were found to be normally distributed. The results were considered significant at a 95% confidence level and a p value of <0.05. The receiver operating characteristic analysis was performed to determine the cut-off value of IMA. Multivariate analysis was not performed in this study.

RESULTS

The study included a total of 300 cases, of which 150 were in the CAP group and 150 were in the control group. In the CAP group, 38% (n=57) of the patients were female and 62% (n=93) were male, while 47.3% (n=71) of the controls were female and 52.7% (n=79) were male. The mean age of the 150 patients diagnosed with CAP was 61.03 \pm 1.7 years, and that of the control group was 58.0 \pm 10.6 years (p=0.082). There was no significant difference in age and gender between the two groups (p=0.102 and p=0.082, respectively). The mean IMA levels were 77.97 \pm 6.17 in the CAP group and 77.01 \pm 7.51 in the control group. There were not significant differences between

the two groups in terms of the IMA levels ($p=0.742$). The demographic data and laboratory findings of the patients with CAP are shown in Table and their comorbidities in Figure 1 according to the outpatient, inpatient and intensive care groups. The mean age of the outpatient group was statistically significantly lower than the other two groups ($p=0.035$). There were no significant differences in gender between the three groups ($p=0.794$). IMA was 74.77 ± 5.57 ABSU in the outpatient patients, 78.58 ± 6.01 ABSU in the inpatient patients and 80.60 ± 5.97 ABSU in the intensive care patients. Accordingly, IMA was statistically significantly lower in the outpatient patients compared to the inpatient patients and those receiving intensive care ($p=0.004$ and $p=0.001$, respectively). The distribution of the mean IMA values between the groups is shown in Figures 2 and 3. The CRP value of the outpatient patients was statistically significantly lower than those of the inpatient and intensive care patients ($p=0.001$ and $p=0.003$, respectively).

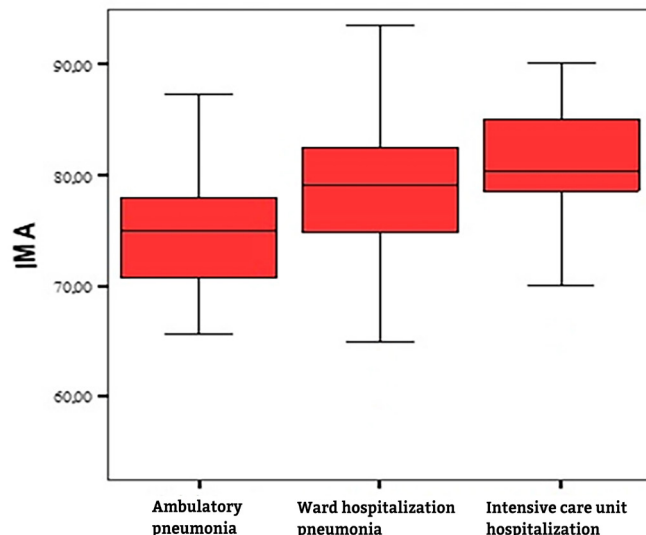


Figure 2. Distribution of IMA values among the community-acquired pneumonia cases
IMA: Ischemia modified albumin

Table. Comparison of the demographic data and laboratory findings between the three CAP groups

| | Ambulatory treatment n=36 (PSI I-III) | Hospitalized in ward n=92 (PSI IV-V) | Admitted to intensive care unit n=22 | p value |
|----------------------|---------------------------------------|--------------------------------------|--------------------------------------|---------|
| | Mean±SD | Mean±SD | Mean±SD | |
| Gender, n (%) | | | | |
| Female | 12 (33.3) | 36 (39.1) | 9 (40.9) | 0.794 |
| Male | 24 (66.7) | 56 (60.9) | 13 (59.1) | |
| IMA (ABSU) | 74.77±5.57 | 78.58±6.01 | 80.60±5.97 | 0.001 |
| CRP (mg/L) | 63.64±69.05 | 156.42±105.49 | 153.26±107.92 | 0.001 |
| SaO ₂ (%) | 96.23±1.79 | 88.08±9.08 | 84.68±9.68 | 0.001 |

SD: Standard deviation, CAP: Community acquired pneumonia, PSI: Pneumonia Severity Index, IMA: Ischemia-modified albumin, CRP: C-reactive protein, SaO₂: Oxygen saturation

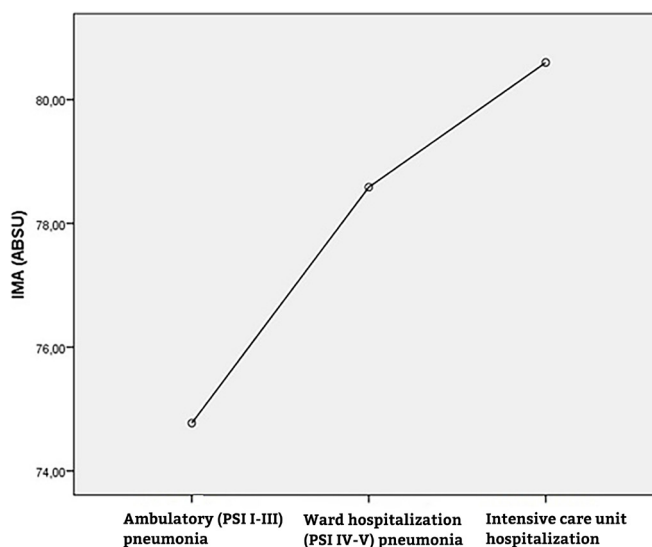


Figure 3. Distribution of ischemia modified albumin (IMA) levels between the study groups
IMA: Ischemia modified albumin, ABSU: Absorbance units

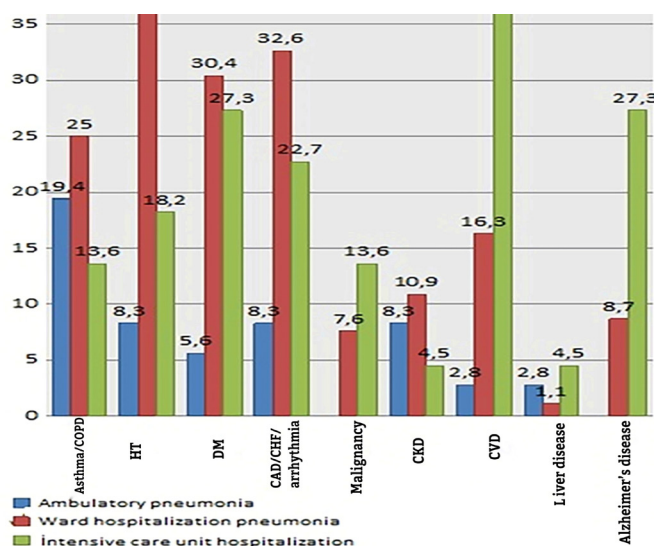


Figure 1. Distribution of comorbidities in the patient group with community-acquired pneumonia (%)
COPD: Chronic obstructive pulmonary disease, HT: Hypertension, DM: Diabetes mellitus, CKD: Chronic kidney disease, CVD: Cerebrovascular disease

When the relationship between IMA and CRP was analyzed within the CAP group, a statistically significant positive correlation was detected ($r=0.343$; $p=0.001$). The results of this analysis are shown in Figure 4.

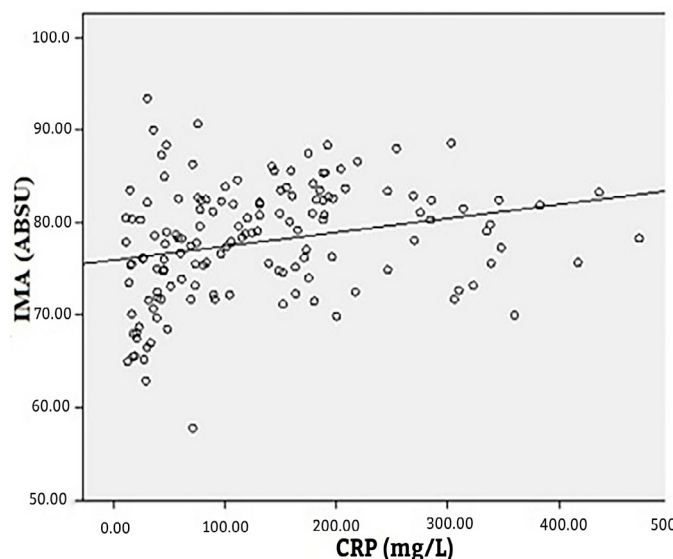


Figure 4. IMA-CRP correlation in the community-acquired pneumonia group
IMA: Ischemia modified albumin, ABSU: Absorbance units, CRP: C-reactive protein

To determine whether an IMA cut-off value could be determined for patients hospitalized due to CAP, the patients were evaluated in two groups as outpatient patients and hospitalized patients (both inpatient and intensive care unit). The area under the curve for the serum IMA levels was 0.708 ± 0.049 (95% confidence interval = 0.612-0.804) $p < 0.001$, cut-off value was 77.60 ABSU, sensitivity was 64.9%, specificity was 75.0%, positive predictive value was 89.2%, and negative predictive value was 40.3% (Figure 5).

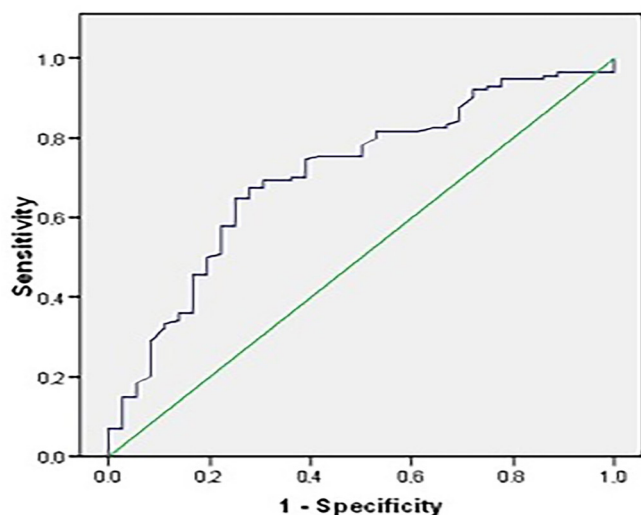


Figure 5. ROC curve demonstrating the correlation between community-acquired pneumonia and IMA
ROC: Receiver operating characteristic, IMA: Ischemia modified albumin

DISCUSSION

In this study, although the serum IMA levels were found to be statistically similar between the CAP and control groups, they were significantly lower among the outpatient patients compared to the inpatient and intensive care groups. In addition, the IMA levels were positively correlated with the CRP levels in the CAP group. These results suggest that IMA levels may be useful in the evaluation of the severity of CAP cases. In addition, they may assist the physician in determining critically ill patients and making a decision for hospitalization.

While death due to infectious diseases continues to decrease with the widespread use of antibiotics and active immunization policies, CAP remains an important lower respiratory tract infection with a high risk of mortality and morbidity. In CAP, disease severity and prediction of clinical outcomes are prerequisites to manage health resources and provide sufficient treatment options. This involves decisions regarding hospitalization in the inpatient or intensive care unit, early discharge and antimicrobial therapy evaluation. To reduce the rate of unnecessary hospitalization, professional organizations have developed prediction rules (CURB-65, PSI) for classification based on the mortality risk of patients with CAP. Since the CURB-65 and PSI scoring systems are only moderately sensitive and specific in determining the risk in patients with CAP, there is still an emphasis on the need for additional risk factors and prognostic markers to improve the prognostic performance of risk scores.¹⁸

IMA is a new acute coronary syndrome marker found to be associated with oxidative stress. Recent studies have revealed

that in addition to its role in acute coronary syndrome, IMA can also play a role in many pathological processes, including pneumonia that alter the balance between oxidant-antioxidant systems. The lung is one of the organs that is most affected by oxidants, and therefore pneumonia is expected to affect the level of IMA.

In the current study, when the CAP cases were compared with the control group, there was no statistically significant difference in terms of the serum IMA levels ($p > 0.05$). In a prospective case-control study by Bolatkale et al.,¹⁹ it was shown that the serum IMA levels significantly increased compared with the healthy controls. To our knowledge, that study was the first to analyze the serum IMA levels in adult patients admitted to the emergency department with CAP. The authors showed, for the first time, that IMA could be a new biomarker that was sensitive for and specific to CAP diagnosis in patients diagnosed in the emergency department. In our study, there was no statistically significant difference between the CAP cases and the control group in terms of the IMA levels. There were 150 subjects in our patient group and 150 subjects in our control group. Of the patients in the CAP group, 22 were admitted to the intensive care unit, 92 were hospitalized in the inpatient, and 36 received outpatient care. In a study by Bolatkale et al.,¹⁹ the case group comprised 81 subjects and the control group comprised 81 subjects. In the case group, six patients required intensive care, 24 were hospitalized in inpatient, and 51 received outpatient treatment. The incompatibility between the results of our study and the findings of Bolatkale et al.¹⁹ can be attributed to the differences in the number of individuals in the patient and control groups. Moreover, in the current study, the IMA value of the outpatient patients was found to be statistically significantly lower than the inpatient and intensive care patients. To our knowledge, there are no studies in the literature that evaluate pneumonia severity and IMA levels according to disease prognosis. In light of our findings, we concluded that serum IMA levels may be useful as a biomarker in the evaluation of severity of CAP cases, making a decision to admit the patient to the inpatient or intensive care unit, and patient follow-up.

We observed a statistically significant correlation between IMA and CRP in the pneumonia group. Similarly, in a study by Bolatkale et al.,¹⁹ a positive correlation was detected between CRP and IMA. Acute inflammatory conditions such as CAP are characterized by the inflammation of pulmonary parenchyma as a response to an infectious event involving systemic and local cytokine secretion and neutrophil uptake. Excessive cytokine production triggers an inflammatory response that can cause organ failure and death. Severity of the infection is correlated with the degree of the inflammatory response of the immune system.²⁰ Specifically, CRP has superior diagnostic value in bacterial infections with a high plasma concentration. However, in majority of viral infections, CRP levels remain normal or increase only slightly.²¹ A recent study reported a significant correlation between CRP and mortality and defined CRP as an independent risk factor for 30-day mortality.²² Regarding inflammatory markers, recent studies have found that CRP has limited diagnostic value for pneumonia at the first step in cases where the probability of pneumonia is below 10%.²³

According to our study, the serum IMA levels, which were correlated with CRP, may be useful as a biomarker reflecting disease severity rather than diagnosis and follow-up of infectious processes such as pneumonia.

PSI is an important index to determine the prognosis and mortality of patients.²⁴ In our study where we classified the patients with CAP according to PSI, we determined that the IMA level could be an important parameter in deciding whether a patient should be hospitalized and predicting the prognosis of CAP. In addition, IMA is similar to other biomarkers in terms of cost, which can be considered as another advantage of this parameter.

Limitations

This study has several limitations that should be considered when interpreting the findings. First, it was conducted in a single center, which may limit the generalizability of the results to different populations and healthcare settings. Although the overall sample size was relatively adequate, the number of patients requiring intensive care was limited, which may have affected the strength of subgroup analyses related to severe disease. Serum IMA levels were measured only at the time of admission, and serial measurements during treatment and follow-up were not performed. Therefore, the potential value of dynamic changes in IMA levels for monitoring treatment response or predicting clinical outcomes could not be evaluated. In addition, the reference range and expected variation of IMA levels in pulmonary infections have not yet been clearly established, making it difficult to interpret the results within a standardized clinical framework. Smoking status was not recorded in either the patient or control groups. Given the known association between smoking, oxidative stress, and albumin modification, this may have influenced serum IMA levels and introduced a potential confounding factor. Another important limitation of this study is the lack of detailed comorbidity data in the control group. Since comorbid conditions may influence oxidative stress and IMA levels, this may have affected the comparability between groups and contributed to the observed findings. Another limitation of this study is that multivariate analysis was not performed to adjust for potential confounding factors such as age, comorbidities, and inflammatory markers.

CONCLUSION

In this prospective case-control study, serum IMA levels were not significantly different between patients with CAP and healthy controls; however, IMA levels were significantly higher in hospitalized patients compared with outpatient cases. Moreover, a positive correlation was observed between IMA and CRP levels, suggesting that IMA may reflect inflammatory burden and disease severity rather than the presence of pneumonia itself. Although IMA does not differentiate CAP patients from healthy individuals, it may serve as an adjunctive biomarker for assessing disease severity and supporting hospitalization decisions. Its diagnostic value appears limited, but its association with clinical severity suggests a potential role in risk stratification.

ETHICAL DECLARATIONS

Ethics Committee Approval

This study was approved by the Clinical Researches Ethics Committee of Ankara Yıldırım Beyazıt University (Date: 02.04. 2018, Decision No: 73).

Informed Consent

Written informed consent was obtained from all individual participants prior to their inclusion in the study. Participants were fully informed about the study's aims, procedures, potential risks and benefits, and their rights-including the right to withdraw at any time without consequence. All participants voluntarily signed a written informed consent form.

Peer Review Process

This manuscript was subject to external peer review.

Conflict of Interest

The authors declare no conflicts of interest related to this study.

Financial Disclosure

The authors received no financial support for the conduct or publication of this research.

Author Contributions

Concept: MY, EŞP; Design: MY, EŞP; Supervision: EŞP, HCH; Materials: ÖE; Data Collection and/or Processing: MY; Analysis and/or Interpretation: MY, ÖE; Literature Review: MY; Writing the Article: MY; Critical Review: EŞP, HCH, ÖE.

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