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Role of procalcitonin in infected diabetic foot ulcer

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ABSTRACT

Aims: Procalcitonin (PCT) has been recently accepted as a marker for diagnosing infection. The aim of the present study was to determine whether PCT levels are associated with infection severity of diabetic foot ulcers and whether PCT levels would be helpful to differentiate infected diabetic foot ulcer (IDFU) from IDFU associated with other infectious diseases (IDFU + O).

Methods: We prospectively included 123 diabetic patients hospitalized for IDFU. Infection severity of diabetic foot ulcers was graded according to the Infectious Diseases Society of America-International Working Group on the Diabetic Foot clinical classification of diabetic foot infection. Chest radiograph, urinalysis, urine microscopy, urine culture, and blood cultures (if fever was present) were performed for all patients to diagnose other infectious diseases. Laboratory parameters were measured from blood venous samples.

Results: PCT (Spearman's $\rho = 0.338$, $P < 0.001$) and C-reactive protein (Spearman's $\rho = 0.477$, $P < 0.001$) levels were significantly associated with infection severity of diabetic foot ulcers. However, only PCT levels could differentiate patients with associated infectious diseases from patients with no concomitant infection (area under the receiver-operator characteristic curve 0.869, $P < 0.0001$; cut-off value 0.59; sensitivity 94.7; specificity 88.5).

Conclusion: PCT and CRP levels positively correlated with infection severity of diabetic foot ulcers and PCT levels > 0.59 ng/mL in patients with IDFU may be associated with other systemic bacterial infection.

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1. Introduction

Approximately 15–25% of diabetic patients have foot ulcers during their lifetime [1]. Diabetic foot ulcers are frequently infected [2]. Fifty-nine percent of diabetic foot amputations have been attributed to infection and infected diabetic foot ulcer (IDFU) is a major causal factor for lower-limb amputation [3,4].

Conventional laboratory markers, such as erythrocyte sedimentation rate (ESR), white blood cell count (WBC) and C-reactive protein (CRP), cannot differentiate between infectious and non-infectious inflammation and are of limited value in the diagnosis of diabetic foot infection [5–7]. Serum procalcitonin (PCT) level is elevated in patients with systemic bacterial infections and, unlike other markers, it is usually not elevated in patients with inflammation due to viral

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infection or non-infectious diseases. Thus, serum PCT has higher diagnostic accuracy for the diagnosis of bacterial infection than standard biochemical parameters, such as the WBC count and serum CRP levels [8–10]. Hence, there has been an interest in investigating the usefulness of PCT for the diagnosis of diabetic foot infection. It has been reported in the literature that PCT levels have higher efficiency in distinguishing IDFU from a non-infected diabetic foot ulcer, followed by CRP, WBC, and ESR levels, and that the combination of PCT and CRP measurements increase the accuracy of predicting diabetic foot infection [11–13]. We postulated that PCT would be useful to assess the infection severity in diabetic foot ulcers and other infectious diseases. Because diabetic foot infection is progressive and associated with the potential risk of gangrene and limb amputation, diabetic foot infection has a high morbidity and mortality rate [11,14–16]. Therefore, prompt and adequate diagnosis and treatment of diabetic foot infection is critical to reduce the amputation and mortality rate.

The aim of the present study was to determine whether PCT levels are associated with infection severity of diabetic foot ulcers and whether PCT levels are helpful in differentiating IDFU from IDFU + O.

2. Subjects, materials and methods

2.1. Patients

This study was approved by the hospital's Institutional Review Board. Between 2012 and 2015, we prospectively included consecutive diabetic patients hospitalized for infected diabetic foot ulcer. The same foot and ankle surgeon in our department examined all patients in order to grade infection severity, according to the Infectious Diseases Society of America-International Working Group on the Diabetic Foot (IDSA-IWGDF) clinical classification of diabetic foot infection [17] and IDFU was diagnosed if the grade of infection was ≥ 2 . Chest radiograph, urinalysis, urine microscopy, urine culture, and blood cultures (if fever was present) were performed on every patient to diagnose other infectious diseases, such as sepsis, pneumonia, and urinary tract infection. Where an abnormal laboratory test result was obtained or other infectious diseases were clinically suspected, the patient was referred to the department of infectious diseases, in order to confirm the diagnosis of concomitant infectious diseases. Inclusion criteria were as follows: infection grade ≥ 2 according to the IDSA-IWGDF criteria, no history of antimicrobial treatment within the previous 6 months, and no history of surgery in the previous 6 weeks. The exclusion criteria were malignancy, inflammatory disease, and immunosuppressive treatment.

2.2. Laboratory parameters

A venous blood sample was obtained from all patients on admission, before the commencement of antimicrobial treatment, to measure the following: WBC and neutrophil count, ESR, CRP, and PCT. For analyzing the PCT levels, blood samples were collected in serum separating tubes and centrifuged for 20 min at 3500 rpm, after being maintained at room

temperature for 20 min. PCT levels were measured using an electrochemiluminescent immunoassay (ELECSYS BRAHMS procalcitonin, Hennigsdorf, Germany), performed on a Cobas e601 analyzer (Roche Diagnostics, Meylan, France), and the functional detection limit was 0.02 ng/mL. The hospital biochemistry laboratory analyzed the WBC and differential blood counts, CRP, and ESR.

2.3. Statistical analysis

Statistical analyses were performed using the software package SPSS for Windows version 16.0.0 (SPSS Inc., Chicago, Illinois). The Mann-Whitney U test or Kruskal-Wallis test were used to compare the continuous variables. To assess the correlation between the grade of infection severity and laboratory parameters, Spearman rho correlation coefficients were calculated for patients with no associated infectious diseases, to avoid the effect of other causes of infection. Comparisons of the correlation coefficients were performed with the Z-test, using the Fisher's Z transformation. A receiver-operating characteristic (ROC) analysis and the area under the ROC curve (AUC) were calculated to measure the accuracy of the laboratory parameter to distinguish patients with IDFU from patients with IDFU + O. The best cut-off value was calculated, and specificity and sensitivity of the laboratory parameters were determined using the best cut-off value. Comparison of the ROC curves was performed to compare the accuracies of laboratory markers for distinguishing the grades of infection severity. A P value < 0.05 was considered statistically significant. The ROC analyses and Fisher's Z transformation were performed using the MedCalc statistical software version 16.4.1 (MedCalc Software bvba, Ostend, Belgium).

3. Results

A total of 123 patients diagnosed with infected diabetic foot ulcer (grade ≥ 2 , IDSA-IWGDF criteria) were included in this study (mean age 67 years; range, 39–86 years, ± 8.5 years). The distribution of infection according to severity, using IDSA-IWGDF criteria, was as follows: grade 2 (29 patients, 23.6%), grade 3 (82 patients, 66.7%), and grade 4 (12 patients, 9.8%). Nineteen patients (15.4%) had other infectious diseases in addition to IDFU. Of these, 10 (8.1%) patients had pneumonia, 6 (4.9%) patients had a urinary tract infection, and 3 (2.4%) patients had sepsis (Table 1). Among the 3 patients diagnosed with sepsis, one had pneumonia, one had urinary tract infection, and one had pneumonia and urinary tract infection.

In patients without any other infectious diseases, the comparison of laboratory parameters among the grades of infection severity of diabetic foot ulcers is shown in Table 2. There were significant differences in the PCT and CRP levels among the infection grades ($P < 0.001$ for both). The correlation analysis in patients with no other infectious diseases demonstrated that PCT (Spearman's ρ 0.338, $P < 0.001$) and CRP (Spearman's ρ 0.477, $P < 0.001$) positively correlated with the grade of infection severity of diabetic foot ulcers, and there was no significant difference between PCT and CRP (z statistic 1.1886, $P = 0.234$) on comparing the correlation

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