PROGNOSTIC VALUE OF PROCALCITONIN RAPID TEST IN PURULENT INFLAMMATORY DISEASES OF THE MAXILLOFACIAL REGION

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Dental diseases, which exhibit high prevalence within the population, are frequently complicated by odontogenic inflammatory processes in the maxillofacial region (MFR), posing a significant risk of systemic septic complications. Procalcitonin (PCT) is a promising biomarker for the diagnosis of sepsis showing high sensitivity and specificity. However, its prognostic value for purulent inflammatory diseases of the maxillofacial region (PID-MFR) is still understudied. The study aimed to evaluate the diagnostic value of the PCT semi-quantitative rapid test for predicting septic complications in patients with PID-MFR and to evaluate the relationship between PCT levels and clinical/laboratory parameters. The study involved 60 patients (73.3% males, 26.7% females) aged between 21 and 71 years with PID-MFR. Serum PCT levels were determined by a semi-quantitative method. Patients were stratified into two groups: group 1 with PCT > 0.5 ng/mL (23.3%), group 2 with PCT < 0.5 ng/mL (76.7%). Septic complications were observed in 28.57% of patients in group 1, whereas no complications occurred in group 2 (p = 0.001; OR = 0.025). There were no significant differences in clinical and laboratory indicators, number of cellular maxillofacial spaces affected (3.7 ± 1.7), disease duration (5.17 ± 3.39 days), and length of hospital stay (6.50 ± 2.41 bed-days) between groups (p > 0.05). Our findings demonstrate that measuring PCT levels via a semi-quantitative method is an effective and accessible approach to predict septic complications of PID-MFR.

Keywords: procalcitonin, sepsis, purulent inflammatory diseases, maxillofacial region

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ПРОГНОСТИЧЕСКАЯ ЦЕННОСТЬ ЭКСПРЕСС-ТЕСТА НА ПРОКАЛЬЦИТОНИН ПРИ ГНОЙНО-ВОСПАЛИТЕЛЬНЫХ ЗАБОЛЕВАНИЯХ ЧЕЛЮСТНО-ЛИЦЕВОЙ ОБЛАСТИ

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Стоматологические заболевания широко распространены среди населения и нередко осложняются развитием одонтогенных воспалительных процессов челюстно-лицевой области (ЧЛО), что создает потенциальный риск развития септических осложнений. Прокальцитонин (ПКТ) — перспективный биомаркер для диагностики сепсиса, обладающий высокой чувствительностью и специфичностью. Однако его прогностическая ценность при гнойно-воспалительных заболеваниях челюстно-лицевой области (ГВЗ ЧЛО) остается недостаточно изученной. Целью исследования было оценить диагностическую ценность полуколичественного экспресс-теста на ПКТ для прогнозирования септических осложнений у пациентов с ГВЗ ЧЛО, а также изучить взаимосвязь между уровнем ПКТ и клинико-лабораторными показателями. В исследование вошли 60 пациентов (73,3% мужчин, 26,7% женщин) в возрасте 21–71 года с ГВЗ ЧЛО. Уровень ПКТ определяли полуколичественным методом. Пациенты были разделены на две группы: в группе 1 ПКТ > 0,5 нг/мл (23,3%), в группе 2 ПКТ < 0,5 нг/мл (76,7%). Септические осложнения отмечены у 28,57% пациентов группы 1; в группе 2 осложнения отсутствовали (p = 0,001; ОШ = 0,025). Статистически значимых различий по клинико-лабораторным показателям, количеству вовлеченных клетчаточных пространств ЧЛО (3,7 ± 1,7), длительности заболевания (5,17 ± 3,39 дня) и госпитализации (6,50 ± 2,41 койко-дней) между группами не установлено (p > 0,05). Результаты исследования демонстрируют, что определение ПКТ полуколичественным методом является эффективным и доступным способом прогнозирования септических осложнений при ГВЗ ЧЛО.

Ключевые слова: прокальцитонин, сепсис, гнойно-воспалительные заболевания, челюстно-лицевая область

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According to the WHO Global Oral Health Status Report (2022), dental diseases are among the most common disorders affecting approximately 45% of the world's population (3.5 billion people) [1]. In Russia, annual epidemiological data from the Russian Dental Association indicate over 158 million cases of seeking dental care [2]. Among these conditions are lesions of hard dental tissues, pulpitis, and periapical diseases, the advanced stages of which frequently progress to odontogenic inflammatory disorders of the maxillofacial region (MFR)[3]. Data from the Organizational and Methodological Department

of Dentistry and Maxillofacial Surgery (Moscow Healthcare Department) further reveal that 37% of adults seeking specialized maxillofacial surgical care require intervention for localized or severe forms of purulent inflammatory diseases of the maxillofacial region (PID-MFR) [4].

Much of this category of patients require long-term treatment due to disease severity and high risk of complications, mediastinitis, thrombosis of facial veins and cerebral sinuses, meningitis, meningoencephalitis, etc. Systemic inflammatory response syndrome, sepsis, endotoxic shock, multiple organ failure are conventionally distinguished among life-threatening purulent septic complications [5].

Sepsis remains a critical challenge in surgical disciplines, including MFS. However, the role of odontogenic infection in pathogenesis of systemic inflammatory response, sepsis, and the related complications is still poorly understood.

Despite significant advances in modern medicine, driven by pharmacological innovation and the development of novel diagnostic and therapeutic modalities, the global incidence of infectious inflammatory disorders remains persistently elevated [2, 3, 6]. According to the WHO report on the epidemiology and burden of sepsis (2020), sepsis accounts for approximately 49 million cases and 11 million deaths annually, representing 20% of global mortality [7].

Over the past decades, the scientists searched for an optimal method to diagnose septic complications [8]. Serum procalcitonin (PCT) has become a biomarker of particular interest due to its high sensitivity and specificity in distinguishing bacterial infections from other inflammatory etiologies [9, 10]. The association between elevated PCT levels and bacterial infections was first established in 1993 [11].

Under physiological conditions, PCT is synthesized in parafollicular cells (C-cells) of the thyroid gland, where it undergoes proteolytic cleavage by endoplasmic reticulum endopeptidases into calcitonin and inactive byproducts. This process accounts for its negligible serum concentration in healthy individuals. However, during systemic inflammatory response syndrome (SIRS), PCT production shifts to an extra-thyroidal pathway, wherein diverse organs and tissues synthesize PCT in response to bacterial endotoxins and pro-inflammatory cytokines. The molecular mechanisms governing this alternative synthesis pathway remain incompletely characterized [12].

Elevated serum PCT levels are associated with adverse clinical outcomes, underscoring its utility as a biomarker for guiding therapeutic strategies [9]. While numerous studies have validated PCT's diagnostic value for the diagnosis of inflammatory disorders, its prognostic value in PID-MFR remains poorly understood, which determines the relevance of our study.

The study aimed to evaluate the prognostic value of the PCT semi-quantitative rapid test as a screening tool for stratifying the risk of septic complications in patients with PID-MFR and to assess the relationship between PCT levels and clinical and laboratory parameters.

METHODS

A retrospective cohort study with the elements of prospective analytical observational assessment was conducted at the specialized Maxillofacial Hospital for War Veterans, Pirogov City Clinical Hospital No. 1 specializing in maxillofacial surgical care and dental care provision to adult patients. The study was managed by V. A. Belchenko, D. Sci. (Med), Chief Freelance Specialist of Moscow Healthcare Department.

Between March 12, 2024, and September 23, 2024, 1,784 patients with PID-MFR presented to the emergency department. Of these, 60 patients were enrolled in the study. The cohort comprised 44 males (73.3%) and 16 females (26.7%), with ages ranging from 21 to 71 years (mean age 42.07 ± 13.81 years). Among patients 68.3% (n = 41) were employed, 31.7% (n = 19) were not. Patients were admitted to hospital through the following routes: ambulance — 15.00% of patients (n = 9), 103-outpatient clinic — 85.00% (n = 51).

The minimum sample size was calculated using the formula by N. M. Buderer with the 10% confidence interval. In this study, the minimum sample size was 43 patients.

Inclusion criteria: patients with PID-MFR aged 18–75 years; submitted informed consent for evaluation and treatment; patients who had not taken antibiotics prior to hospitalization; stable and relatively stable patients in accordance with the green and yellow flows of the triage system; serum C-reactive protein (CRP) levels ≥180 mg/L; performing ICA Procalcitonin semi-quantitative rapid test.

Exclusion criteria: patients under 18 and over 75 years; patient's refusal to participate in the study or undergo treatment; taking antibiotics before hospital admission by the patient; patients with life-threatening conditions requiring emergent resuscitation, in accordance with the red flow of the triage system; noncompliance with the laboratory criteria and no indications for the ICA Procalcitonin semi-quantitative test.

The literature review revealed significant variability of CRP levels among patients with PID-MFR. According to the results of the study focused on early diagnosis of sepsis (2021), the range of CRP concentrations was 82.50–95.35 mg/L [13]. In another study (2021) the mean CRP level of 140 mg/L associated with odontogenic infections was reported [14]. According to the data of the study conducted in 2024, the mean CRP admission levels were 185.2 mg/L in males and 189.4 mg/L in females [15]. Based on this evidence, we established a diagnostic CRP threshold of ≥180 mg/L [13–15].

All patients admitted to the emergency department underwent standardized triage assessment. The triage criteria for stratifying patients into green (stable), yellow (semi-stable), and red (critical) categories are summarized in Table 1.

Initial clinical evaluations were conducted by a multidisciplinary team comprising a maxillofacial surgeon and a general practitioner. The following additional tests were performed immediately after evaluation: 1) laboratory analyses — complete blood counts and urinalysis, blood biochemistry panel, coagulation profile; 2) imaging studies — computed tomography (CT) of the chest and maxillofacial region. Based on the evaluation results and inclusion criteria, patients were selected and blood PCT levels were determined by a semi-quantitative method using the ICA Procalcitonin 500 rapid test (Akademinnovacija LLC, Russia) (Fig. 1).

The ICA Procalcitonin 500 assay (Akademinnovatsiya LLC, Russia) is an *in vitro* immunochromatographic rapid test designed for semi-quantitative determination of procalcitonin (PCT) levels in human serum and plasma. The method is based on the immunochromatography analysis principles. When the patient's blood serum or plasma (four drops) is applied to the test strip, interaction with specific monoclonal antibodies against PCT conjugated with the stained marker occurs. The complex produced passes through the test zone with the specific antibodies immobilized on the membrane and forms the stained complex: immobilized antibodies – procalcitonin – antibodies with the marker. The emergence of two parallel stained lines (C and T) in the test window of the cassette indicates a positive result, i.e. that the PCT concentration

Table 1. Triage system criteria for identifying patients into green, yellow and red flows

Indicator	Green flow	Yellow flow	Red flow
HR, bpm	60–90	40–60 90–100	< 40 > 130
RR, per 1 min	8–16	16–25	> 30
BP, mmHg	110/60–140/110	<110/60 >140/110	< 75/30 > 240/140
SpO_2, %	> 95	92–95	< 90
T °C	36.0–37.5	35.0–36.0 37.5–39.0	< 35.0 > 40.0
Morse Fall Scale	0–25	25–50	> 50
Glasgow Coma Scale	15	14	< 13
Pain scale	1–3	4–7	8–10

exceeds 0.5 ng/mL. The presence of only one stained control line (C) indicates a negative result, i.e. that there is no PCT in the sample or that PCT concentration is below 0.5 ng/mL. The lack of stained lines in the test window or the emergence of the test line (T) only indicates that the test result is invalid.

The decision on patient management tactics was made based on the evaluation results: hospitalization and surgical treatment in the specialized hospital or transfer to the multidisciplinary hospital.

Retrospective data acquisition and analysis of the patients' medical records (003/u form) were conducted. The study results obtained were entered in the table and subjected to statistical processing using the StatTech v. 4.0.5 software package (StatTech, Russia).

The statistical analysis conducted included testing the distribution of quantitative indicators for normality using the Kolmogorov–Smirnov test. The normally distributed parameters were presented as the mean (M) with the standard deviation (SD) and 95% confidence interval (CI), while categorical data were presented as absolute values and percentage with the 95% CI calculated by the Clopper–Pearson method. Groups were compared based on quantitative traits using the Student's t-test for samples with equal variances and Welch's *t*-test for samples with unequal variances. Qualitative indicators were analyzed using the Fisher's exact test for contingency tables. The effect size was assessed via odds ratio with the 95% CI; the Haldane–Anscombe correction was applied, when there were zero values in the cells of the table. In all cases, the differences were considered significant at $p < 0.05$.

RESULTS

Patients were stratified into two cohorts based on serum PCT levels measured via the ICA Procalcitonin semi-quantitative immunochromatographic assay. Group 1 (n = 14, 23.3%) comprised individuals with elevated PCT concentrations (>0.5 ng/mL), while Group 2 (n = 46, 76.7%) included patients with subthreshold PCT levels (<0.5 ng/mL). Comparative analyses of the patient groups are provided in Table 2.

The time from symptom onset to seeking care ranged from 1 to 21 days, with a mean of 5.17 ± 3.39 days (95% CI: 4.29–6.04).

The number of the cellular maxillofacial spaces affected by inflammation varied between 1 and 8 with the mean value of 3.7 (95% CI: 3.27–4.13). The mode value for this parameter was 4.00 (Fig. 2).

The analysis of etiological factors showed that in 50.0% of cases (n = 30) the development of PID-MFR was associated with exacerbation of chronic periodontitis in permanent teeth, mostly mandibular molars. Extraction of permanent teeth in outpatient settings caused inflammation in 31.67% of cases (n = 19), and in 18.33% of cases (n = 11) inflammation was attributed to permanent tooth extractions performed in outpatient settings Acute pericoronitis in the mandibular third molars was diagnosed in 6.67% of patients (n = 4). In rare cases,

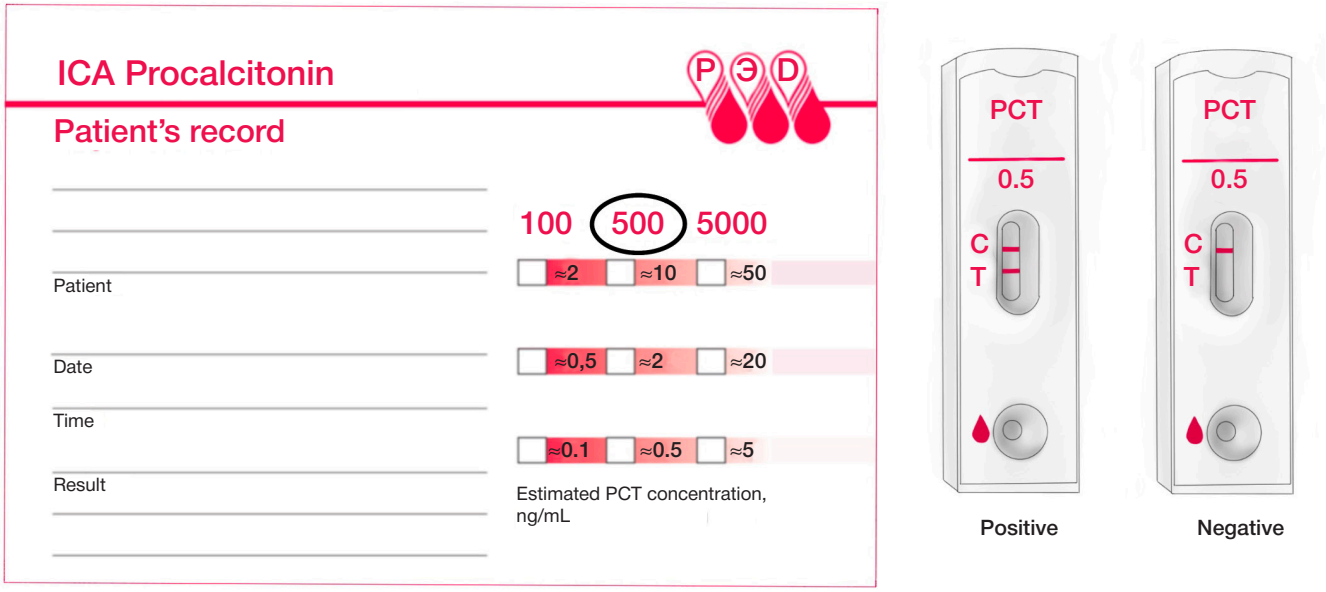

Fig. 1. ICA Procalcitonin 500 test kit (drawing by the author)

Table 2. Comparative characteristics of the studied patient groups

Clinical characteristics	PCT > 0.5 ng/mL	PCT < 0.5 ng/mL
Sex	Males — 85.71% (*n* = 12) Females — 14.29% (*n* = 2)	Males — 69.57% (*n* = 32) Females — 30.43% (*n* = 14)
Age	46.21 ± 17.40 years	40.80 ± 12.48 years
Diagnosis	K12.2 — 14.29% (*n* = 2) L03.2 — 85.71% (*n* = 12)	K12.2 — 19.57% (*n* = 9) L03.2 — 80.43% (*n* = 37)
Concomitant disorders	Cardiovascular disorders — 42,86% (*n* = 6) Diabetes mellitus — 7.14% (*n* = 1) Respiratory disorders — 7.14% (*n* = 1)	Cardiovascular disorders — 30.43% (*n* = 14) Gastrointestinal disorders — 10.87% (*n* = 5) Obesity — 42.86% (*n* = 6) Anemia — 10.87% (*n* = 5) Nervous system disorders — 6.52% (*n* = 3) Impaired glucose tolerance — 6.52% (*n* = 3) Diabetes mellitus — 4.34% (*n* = 2)
Average time since the disease onset	5.79 ± 5.04	4.98 ± 2.75
Average number of bed-days among individuals treated entirely in hospital settings	7.6 ± 1.80	7.02 ± 1.44
Surgical approach	Intra-oral — 14.29% (*n* = 2) External — 64.29% (*n* = 9)	Intra-oral — 19.57% (*n* = 9) External — 80.43% (*n* = 37)

(1.67%, *n* = 1), etiological factors included acute suppurative parotitis, complications after root canal therapy of mandibular second molars, peri-implantitis, post-traumatic osteomyelitis following mandibular fracture, and wound infection.

Among all patients, 95% (n = 57) were admitted to the 24-hour inpatient department of the MFS. After pre-hospitalization evaluation, 3.33% of patients (*n* = 2) required transfer to multidisciplinary hospital due to acute decompensation of preexisting comorbidities exacerbated by SIRS. Another 1.67% of patients (*n* = 1) were transferred to mitigate risks of intraoperative and postoperative complications associated with acute edematous-infiltrative laryngitis.

Depending in inflammation localization, the inflammatory focus debridement was performed via intra-oral route in 18.33% (*n* = 11), via external route in 76.67% (*n* = 46).

Surgical debridement of inflammatory foci was performed through either intraoral or external approaches, depending on the anatomical localization of the infectious process. The intraoral approach was used in 18.33% of cases (*n* = 11), while the external approach was used in the majority of patients (76.67%, *n* = 46).

During surgical procedures biomaterial was collected from all patients for culture-based microbiological analysis. According to microbiological testing results, the most common pathogens causing PID were *Streptococcus viridans* — 31.58% (*n* = 18) and *Neisseria spp*. — 14.04% (*n* = 8). Colonies of *Streptococcus oralis* — 10.52% (n = 6), *Streptococcus constellatus* — 7.01% (*n* = 4), *Streptococcus pyogenes* — 7.01% (*n* = 4), *Streptococcus anginosus* — 5.26% (*n* = 3), *Staphylococcus aureus* — 3.51% (*n* = 2), *Staphylococcus warneri* — 3.51% (*n* = 2), *Eikenella corrodens* — 1.75% (*n* = 1), *Enterobacter cloacae* — 1.75% (*n* = 1), and *Acinetobacter baumannii* — 1.75% (*n* = 1) were less frequent. Polymicrobial communities, predominantly comprising *Streptococcus viridans* and *Neisseria spp*., were identified in 14.04% of cases (*n* = 8). No microbial growth was observed in 17.54% of specimens (*n* = 10).

The length of hospitalization ranged from 4 to 11 bed-days, with a medico-economic standard (MES 73.180) of 8 bed-days. Patients with procalcitonin (PCT) levels >0.5 ng/mL exhibited a mean hospital stay of 7.6 ± 1.80 bed-days, compared to 7.02 ± ± 1.44 bed-days in those with PCT levels <0.5 ng/mL. The overall mean hospitalization duration was 6.50 ± 2.41 bed-days.

No significant correlation was observed between PCT levels and inflammatory biomarkers (C-reactive protein, leukocyte count, fibrinogen) in patients with PID-MFR ($p > 0.05$, Student's *t*-test and Welch's *t*-test).The results are provided in Fig. 3.

PCT levels showed no association with clinical parameters, including hospitalization duration, number of involved maxillofacial

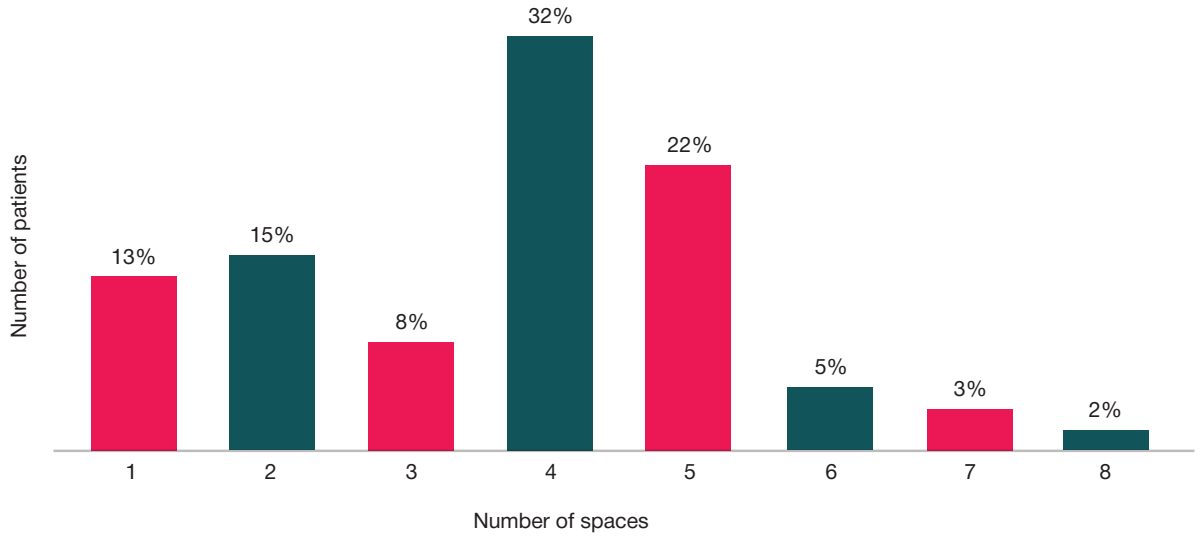

Fig. 2. Mode of the number of cellular maxillofacial spaces affected by inflammation

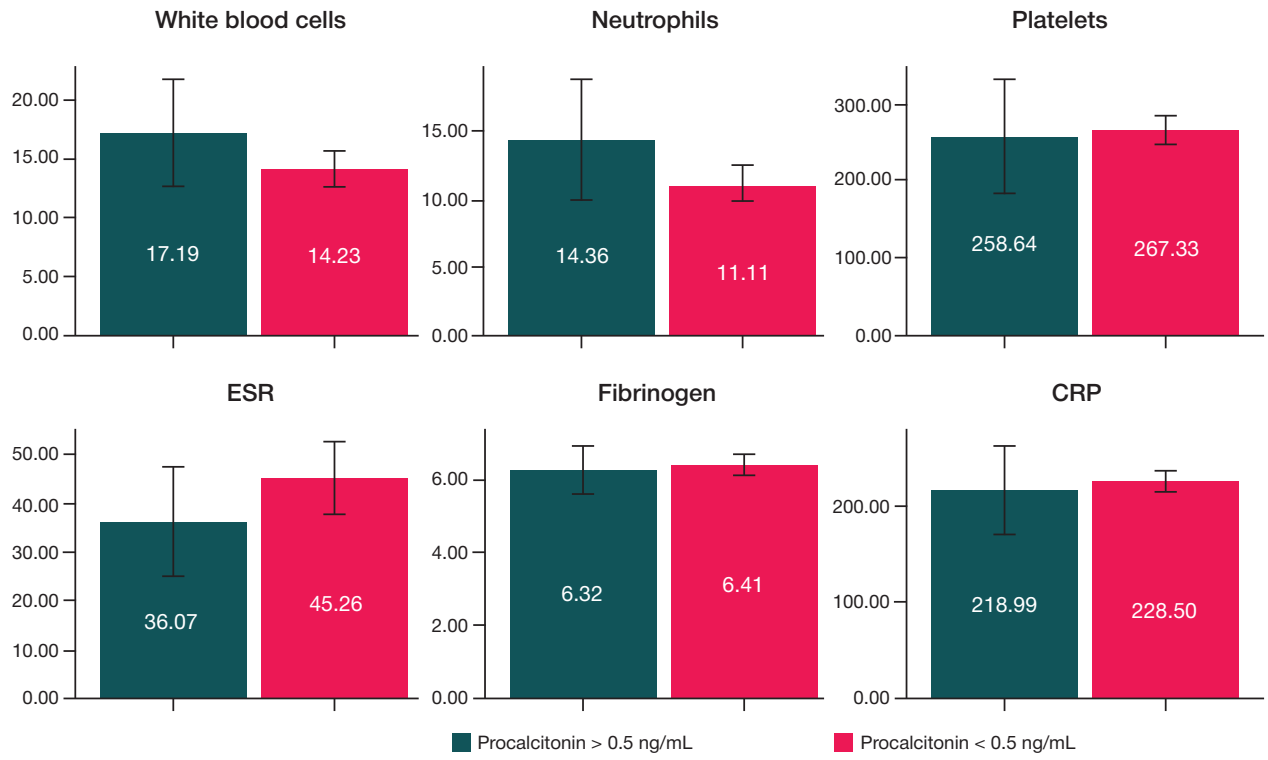

Fig. 3. Dependence of the main inflammation biomarkers on procalcitonin levels

fascial spaces, or disease progression time ($p > 0.05$; Student's *t*-test and Fisher's exact test).

Complications such as SIRS, sepsis, and endotoxic shock were diagnosed in 28.57% of PCT-positive patients ($n = 4$), with a statistically significant odds ratio (OR = 0.025; 95% CI: 0.001–0.503; $p = 0.001$, Fisher's exact test; Fig. 4). The analysis of the results are provided in Fig. 4.

Patients with negative PCT results demonstrated a 39.86-fold lower risk of complications compared to the PCT-positive cohort (OR = 0.025; 95% CI: 0.001–0.503).

Age did not significantly influence complication risk ($p > 0.05$; Student's *t*-test; Fig. 5).

Positive prognostic value of the ICA Procalcitonin 500 semi-quantitative test was 28.57%.

DISCUSSION

The incidence of septic complications in PID-MFR remains relatively low. A retrospective analysis of 483 PID-MFR patients revealed sepsis in only 3.3% of cases [16]. Nevertheless, the potential for life-threatening complications necessitates a multidisciplinary approach to diagnosis and treatment, particularly in severe PID-MFR cases characterized by systemic involvement.

In 2001–2016, sepsis diagnosis relied on the presence of ≥2 SIRS criteria. However, the limited specificity of SIRS prompted a paradigm shift in 2016 with the publication of the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3), which redefined sepsis as life-threatening organ dysfunction arising from a dysregulated host response to infection [17]. Representation of odontogenic sepsis pathogenesis is provided in Fig. 6.

Standard clinical and laboratory inflammatory markers, such as CRP and leukocyte counts, demonstrate limited predictive accuracy for severe septic complications. Early diagnosis facilitated by biomarkers like PCT enables timely therapeutic intervention, which is critical for improving patient outcomes. The results of our study confirm that PCT is a reliable

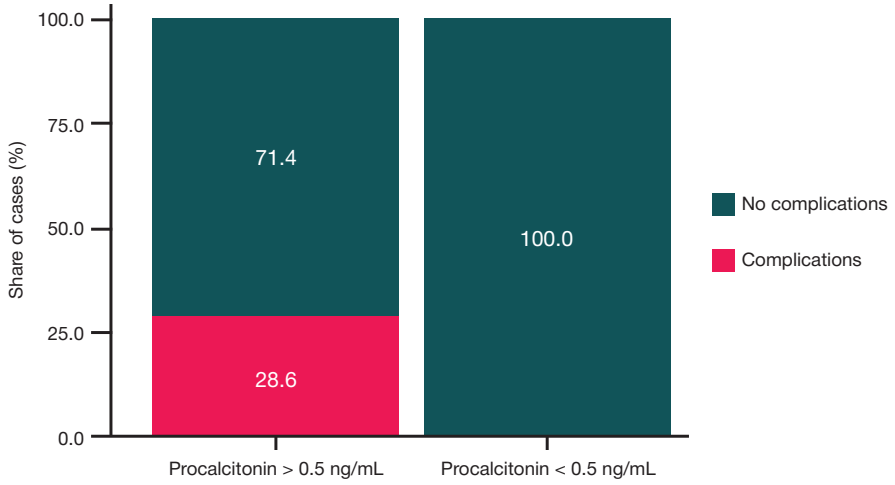

Fig. 4. Analysis of the development of complications depending on procalcitonin levels

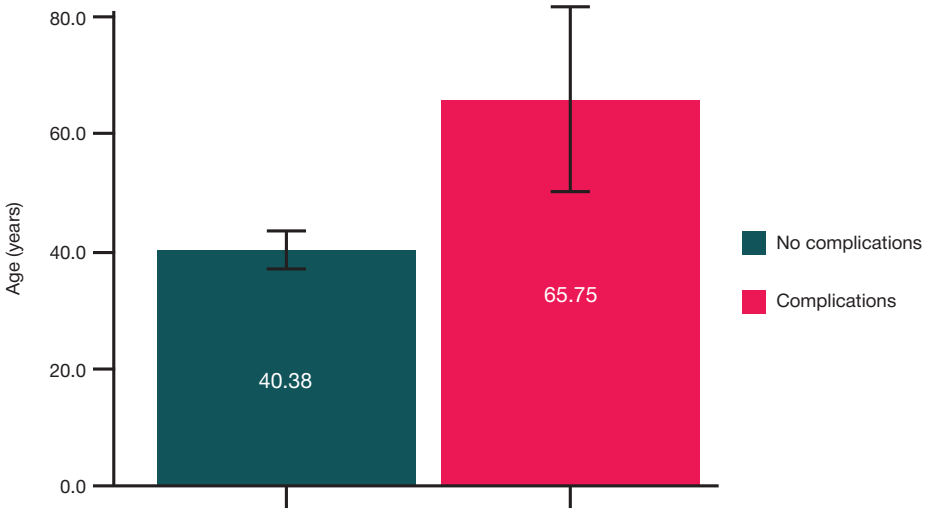

Fig. 5. Analysis of the development of complications depending on the patient's age

prognostic marker of sepsis [8, 10, 18]. A major advantage of PCT is its early appearance in blood serum — within 3–4 hours of synthesis — with peak concentrations reached at 6–12 hours and a half-life of approximately 24 hours. Under effective treatment, PCT levels typically decrease by 50% per day. In contrast, microbiological diagnostic methods require at least 48 hours and may yield false-negative results in 60–70% of cases [8, 18]. Thus, determination of PCT levels using the ICA Procalcitonin 500 rapid test and analogues ensures fast decision-making, thereby significantly improving the patient's outcome.

In this study we analyzed clinical and laboratory data of two groups of patients with PID MFR, 23.33% of patients

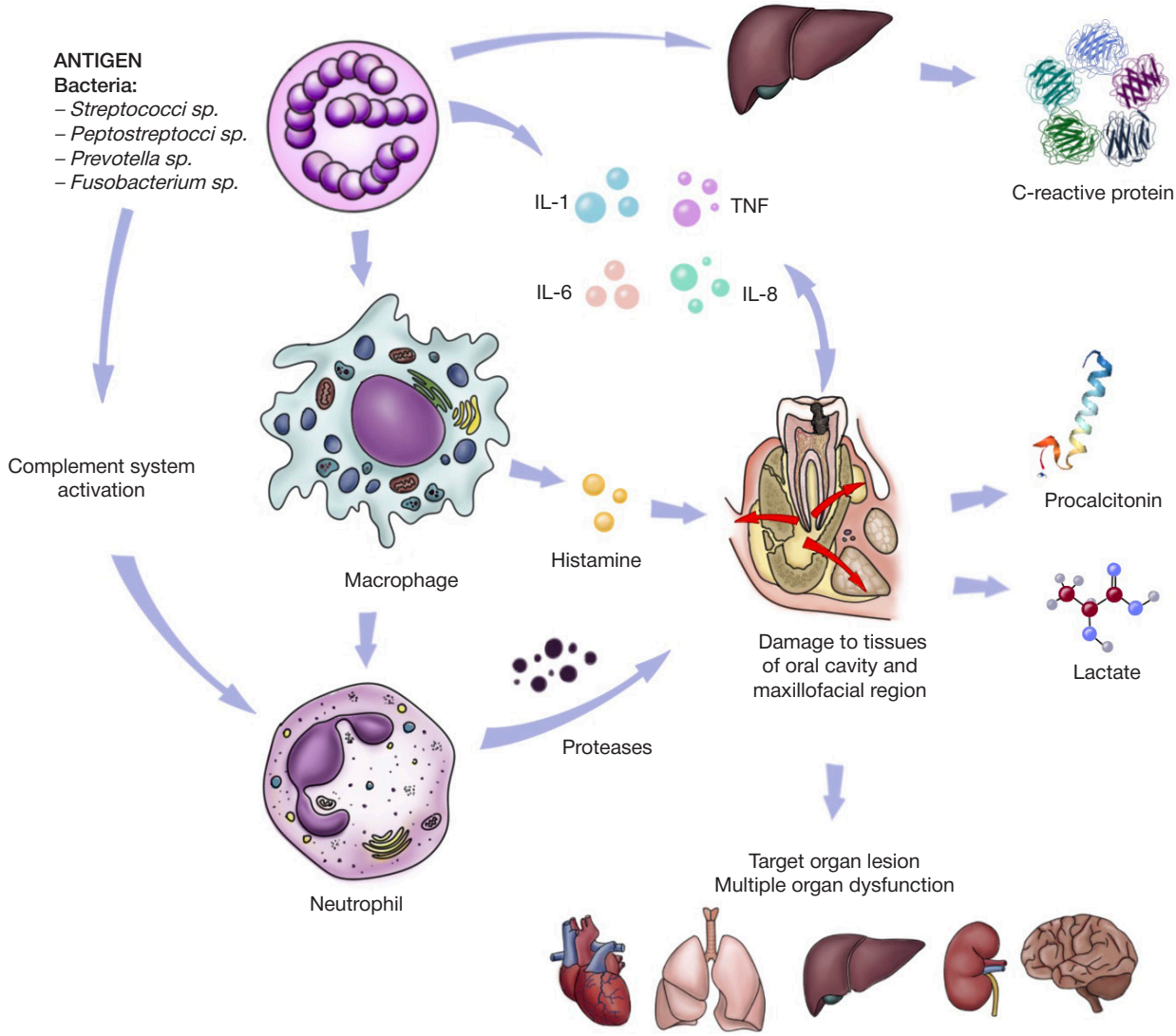

Fig. 6. Sheme of odontogenic sepsis pathogenesis (drawing by the author)

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tested positive for elevated PCT levels, with 28.57% of this subgroup developing complications such as SIRS or sepsis. No significant differences were found between the groups with regard to key clinical and laboratory indicators, including hospital stay duration, number of affected fascial spaces, disease duration, leukocyte, neutrophil and platelet counts, ESR, CRP, and fibrinogen levels. However, a significant correlation was observed between a positive PCT test result, increased patient age, and the risk of developing complications related to PID-MFR. These findings are consistent with the results reported in previous studies, supporting the use of PCT testing as a screening tool in the clinical practice of maxillofacial surgery [14, 18].

One of the limitations of the study is the relatively small sample size.

The predominance of outpatient referrals (85%) underscores the assay's potential for pre-hospital risk stratification. The semi-quantitative PCT test combines diagnostic efficacy, operational simplicity, and rapid turnaround, making it a promising screening method for identifying and predicting complications in both outpatient and inpatient settings.

CONCLUSIONS

The semi-quantitative rapid PCT test demonstrates effectiveness in stratifying the risk of septic complications among patients with PID-MFR. The absence of significant correlations between PCT levels and conventional inflammatory markers — such as CRP, leukocyte count, and fibrinogen — as well as clinical parameters (hospital stay duration, number of affected fascial spaces) underscores its independent prognostic value in evaluating systemic inflammatory response severity. The positive predictive value of 28.57%, coupled with statistically significant intergroup differences, confirm the clinical feasibility of integrating this assay into routine practice. Implementation of the PCT rapid test aligns with contemporary specialized care standards, facilitating early diagnosis and evidence-based therapeutic decision-making.

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