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The relationship between plasma fibrinogen levels and mortality in patients with sepsis followed in the intensive care unit

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Abstract

Introduction: Sepsis is a clinical picture closely associated with mortality that affects a large number of patients worldwide every year. This condition, which is frequently associated with infection, can also develop due to noninfectious causes such as burns. Sepsis is also associated with disseminated intravascular coagulation (DIC). Fibrinogen is a coagulation factor secreted from the liver. Liver failure, cardiac diseases, malignancies and some chemotherapy drugs may affect fibrinogen levels. Especially fibrinogen tends to decrease due to sepsis. This is of critical importance especially in sepsis-associated DIC.
Materials and Methods: In this retrospective study of 80 patients aged 18-90 years who were hospitalized in the anesthesiology and reanimation intensive care unit, fibrinogen, platelet, WBC, INR, aPTT, CRP, procalcitonin, SOFA and ISTH scores measured on days 0 and 3 were collected and their relationships with mortality were compared. Statistical analyses were performed using SPSS 22.0 for. Comparisons were performed using Chi-square, Kruskal–Wallis, and Mann–Whitney U tests. A p-value <0.05 was considered significant. Patients were divided into 3 groups according to fibrinogen trend.
Results: A total of 80 adults were included and stratified into three groups based on fibrinogen trends: decreased (n=21), stable (n=39), and increased (n=20). to statistical analysis, SOFA and ISTH scores were found to be high in the group with low fibrinogen level (p:0,032 - p:0,005 for SOFA, p:0,026 - p:0,038 for ISTH score, respectively), and WBC, Platelet, Procalcitonin and D-Dimer were found to be high among laboratory parameters (p: 0.013 - p:0.020 for WBC, p:0.030 for Platelet, p:0.009 - p:0.008 for Procalcitonin, p:0.001 - p:0.008 for D-Dimer, respectively) and mortality was higher in the group with decreased fibrinogen level compared to the other groups (p<0.001).
Discussion: In sepsis and DIC, it is critical to rapidly diagnose, initiate treatment and predict mortality. Although many scoring systems have been developed for this purpose, SOFA is the most commonly used scoring system for sepsis and ISTH for DIC. According to our results, SOFA and ISTH scoring systems as well as decreased fibrinogen level can be used to predict mortality. Decreased fibrinogen level in sepsis can be used as a predictor of mortality.

Keywords: Disseminated intravascular coagulation, sepsis, coagulation, fibrinogen.

Yoğun bakım ünitesinde takip edilen sepsis tanılı hastaların plazma fibrinojen düzeylerinin mortalite ile ilişkisi

Öz

Giriş: Sepsis dünya genelinde her yıl çok sayıda hastanın etkilendiği mortaliteyle yakından ilişkisi olan klinik bir tablodur. Sıklıkla enfeksiyonla ilişkili olan bu durum yanık gibi nonenfeksiyöz nedenlere bağlı olarak da gelişebilmektedir. Sepsis aynı zamanda dissemine intravasküler koagülasyon (DİK) ile karşılıklı ilişkisi bulunan bir durumdur. Fibrinojen karaciğerden salgılanan bir koagülasyon faktörüdür. Karaciğer yetmezliği, kardiyak hastalıklar, maligniteler ve bazı kemoterapi ilaçları fibrinojen seviyesini etkileyebilmektedir. Özellikle fibrinojen sepsise bağlı olarak azalma eğilimindedir. Bu durum özellikle sepsise bağlı gelişen DİK tablosunda kritik bir öneme sahiptir.
Gereç ve Yöntem: Kanuni Sultan Süleyman hastanesi anesteziyoloji ve reanimasyon yoğun bakım ünitesinde yatmış olan 18-90 yaş arasındaki 80 hastada retrospektif olarak yapılan bu çalışmada 0.ve 3.günlerde ölçülmüş olan fibrinojen, platelet, WBC, INR, aPTT, CRP, prokalsitonin değerleri ile birlikte SOFA ve ISTH skorları toplanmış ve mortalite ile olan ilişkileri karşılaştırılmıştır. İstatistiksel analizler SPSS 22.0 for kullanılarak yapılmıştır. Fibrinojen trendine göre hastalar 3 gruba ayrılmıştır.
Bulgular: İstatistiksel analize göre fibrinojen seviyesi düşük olan grupta SOFA ve ISTH skorları yüksek bulunmuş (SOFA için sırasıyla p:0,032 – p:0,005, ISTH skoru için sırasıyla p:0,026 – p:0,038), laboratuvar parametrelerinden WBC, Platelet, Prokalsitonin ve D-Dimer yüksek bulunmuştur (WBC için sırasıyla p:0,013 – p:0,020, Platelet için p:0,030, Prokalsitonin için sırasıyla p:0,009 – p:0,008, D-Dimer için sırasıyla p:0,001 – p:0,008) ve mortalite için fibrinojen seviyesi azalmış olan grupta mortalite diğer gruplara kıyasla daha yüksek bulunmuştur (p<0,001).
Tartışma: Sepsiste ve DİK'te hızlıca tanıyı koyabilmek, tedaviyi başlayabilmek ve mortaliteyi öngörebilmek kritik öneme sahiptir. Bu amaçla çok sayıda skorlama sistemi geliştirilmiş olmakla sepsis için günümüzde en sık kullanılan skorlama sistemi SOFA iken DİK için ISTH skorlamalarıdır. Bizim elde ettiğimiz sonuçlara göre SOFA ve ISTH skorlama sistemleri ile birlikte azalmış fibrinojen seviyesi de mortaliteyi ön görmek amacıyla kullanılabilir. Sepsiste fibrinojen seviyesinde meydana gelen azalma mortalite açısından bir prediktör olarak kullanılabilir..

Anahtar Kelimeler: Dissemine intravascular coagulation, sepsis, koagülasyon, fibrinojen.

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Introduction

Sepsis is a clinical syndrome with increasing global incidence, affecting an estimated 0.4–1 per 1,000 individuals annually in Europe and the United States (1, 2). Given its strong association with mortality, early recognition, effective fluid resuscitation, and timely initiation of therapy are of critical importance.

Disseminated intravascular coagulation (DIC) is one of the most severe complications of sepsis. It is characterized by widespread activation of the coagulation system, leading to microvascular thrombosis, tissue hypoxia, and eventual organ dysfunction(3). Diagnosis of sepsis-related DIC is based on clinical features and coagulation parameters, although conditions such as thrombotic microangiopathy and heparin-induced thrombocytopenia must also be considered in the differential diagnosis (1).

Fibrinogen plays a pivotal role in the pathophysiology of DIC (4). As the most abundant coagulation factor, it serves as a critical substrate for thrombin, leading to fibrin clot formation. In sepsis-induced DIC, fibrinogen levels may decrease, impairing clot formation and increasing the risk of bleeding. For this reason, fibrinogen levels are closely monitored, and supplementation may be required to restore hemostatic balance (5). However, replacement therapy carries the risk of exacerbating thrombotic events, necessitating careful clinical judgment (6).

During sepsis and septic shock, excessive activation of coagulation pathways involves fibrinogen, platelets, tissue factor, multiple clotting factors, anticoagulant proteins, fibrinolytic mediators, and complement components (7). The resulting dysregulation promotes thrombin generation, fibrin deposition, and microthrombus formation, which can compromise organ perfusion. In this study, we aimed to evaluate the prognostic significance of serum fibrinogen levels in patients with sepsis.

Materials and methods

Statement of ethical approval

This study was approved by ethical Committee of Health Science University İstanbul Kanuni Sultan Süleyman Education and Training Hospital on 08/02/2023 with approval number 2023.02.7. It was conducted in accordance with the principles of the Declaration of Helsinki.

Study design and patient selection

This research was designed as a retrospective, single-center, observational cohort study. Patients admitted to the intensive care unit (ICU) between January 1, 2021, and December 31, 2022, with a diagnosis of sepsis were screened. A total of 80 patients aged between 18 and 90 years were included.

Inclusion criteria

- Age between 18 and 90 years
- Diagnosis of sepsis according to Sepsis-3 criteria
- Availability of complete clinical and laboratory records

Exclusion criteria

- History of primary liver disease
- Presence of malignancy
- Incomplete laboratory or clinical data
- Age under 18 or over 90 years

Definition of sepsis

Sepsis was identified according to the Sepsis-3 definition. Patients were considered to have sepsis if they had suspected or documented infection and an acute increase in SOFA score of ≥2 points at ICU admission compared with baseline. Suspected/documented infection was determined from the electronic medical records based on the treating physician's diagnosis and/or initiation of antimicrobial therapy together with supportive evidence (e.g., positive microbiological cultures, imaging findings, or clinical focus of infection).

Data collection

Demographic and clinical characteristics were extracted from electronic medical records:

- Demographics: age, sex
- Clinical data: mortality status (survivor/non-survivor), comorbidities, length of ICU stay (days), source of infection (classified as abdominal, skin, central venous catheter, pulmonary, urinary, or unknown)
- Scores: Sequential Organ Failure Assessment (SOFA) score at ICU admission

Laboratory measurements

Laboratory parameters were recorded on the day of ICU admission (day 0) and on day 3:

- Platelet count (PLT)
- White blood cell count (WBC)
- Procalcitonin (PCT)
- C-reactive protein (CRP)
- International normalized ratio (INR)
- Activated partial thromboplastin time (aPTT)
- Fibrinogen
- D-dimer
- International Society on Thrombosis and Haemostasis (ISTH) score

Definition of fibrinogen trend

The fibrinogen trend was defined by calculating the ratio of fibrinogen value on day 3 to the value on day 0. Based on this ratio, patients were categorized into three groups:

- Decreasing trend: values below the first quartile
- Stable trend: values between the first and third quartiles
- Increasing trend: values above the third quartile

Statistical analysis

All statistical analyses were performed using SPSS version 22.0 (IBM, Armonk, NY, USA). Continuous variables were expressed as median with minimum and maximum values, while categorical variables were presented as percentages. The normality of data distribution was assessed using the Kolmogorov-Smirnov test. The association between fibrinogen trend groups and categorical variables was evaluated using the Chi-square test. Comparisons of continuous variables across fibrinogen trend groups were conducted with the Kruskal-Wallis test, and in cases where statistically significant differences were observed, pairwise comparisons were further performed using the Mann-Whitney U test. A two-tailed p-value of less than 0.05 was considered statistically significant.

Results

Among the 80 patients included in the study, 21 were in the decreased fibrinogen group, 39 in the stable group, and 20 in the increased group. The median age was 70 years (19–87) in the decreased group, 69 years (23–89) in the stable group, and 72 years (21–85) in the increased group. The proportion of males was 71.4% (15) in the decreased group, 53.8% (21) in the stable group, and 40.0% (8) in the increased group. The median SOFA score was 12 (6–14) in the decreased group, 9 (4–14) in the stable group, and 9 (5–12) in the increased group. The sites of infection were abdominal (24), pulmonary (23), urinary (23), unknown (5), skin (3), and central venous catheter (2). Mortality was 85.7% (18) in the decreased group, 28.2% (11) in the stable group, and 20.0% (4) in the increased group; overall mortality was 41.3% (33) (Table 1).

At baseline (Day 0), ISTH scores were significantly higher in the decreased group compared with the other groups. By Day 3, this difference persisted and reached statistical significance. By Day 3, WBC counts remained higher in the decreased group, whereas they declined in the stable and increased groups. Platelet counts were significantly lower in the decreased fibrinogen group on Day 3, whereas they remained relatively preserved in the stable and increased groups (Table 2).

Markers of inflammation followed distinct patterns. Procalcitonin remained markedly elevated in the decreased group, whereas it declined substantially in the stable and increased groups. CRP levels were high in all groups but did not differ significantly over time. Regarding coagulation parameters, PT-INR and aPTT values showed no significant differences among groups. However, fibrinogen was consistently lower in the decreased group compared to others, both at baseline and Day 3. Finally, D-dimer levels were markedly higher in the decreased group throughout follow-up, with significant intergroup differences observed at both time points (Table 2).

Table 1. Clinical Characteristics of the patients

	Decreased (n=21)	Stable (n=39)	Increased (n=20)	Total (n=80)	p-value
Age (years)	70 (19–87)	69 (23–89)	72 (21–85)	69 (19–89)	0.878
Gender (M/F)	15/6	21/18	8/12	44/36	0.127
SOFA score	12 (6–14)[ab]	9 (4–14)	9 (5–12)	10 (4–14)	0.020
Site of infection					0.910
– Unknown	1	2	2	5	
– Abdominal	8	12	4	24	
– Pulmonary	5	10	8	23	
– Skin	1	1	1	3	
– Central venous catheter	1	1	0	2	
– Urinary	5	13	5	23	
Mortality (%)	18(85.7)[ab]	11 (28.2)	4 (20.0)	33 (41.3)	<0.001

[a] p < 0.05 Decreased vs. Stable, [b] p < 0.05 Decreased vs. Increased, [c] p < 0.05 Stable vs. Increased

Table 2. Analysis of Laboratory Parameters

	Time	Decreased (n=21)	Stable (n=39)	Increased (n=20)	Total (n=80)	p-value
ISTH score	Day 0	4 (2–5)[ab]	3 (2–5)	3 (2–5)	3 (2–5)	0.048
	Day 3	4 (2–6)[ab]	3 (2–6)	3 (2–5)	3 (2–6)	0.003
WBC (×10^9/L)	Day 0	15.3 (1.99–27.8)	16.2 (2.66–39.9)	15.8 (2.26–32.4)	15.7 (1.99–39.9)	0.689
	Day 3	16.6 (3.26–31.2)[ab]	11.6 (1.99–33.6)	10.9 (2.54–21.6)	12.4 (1.99–33.6)	0.022
Platelets (×10^9/L)	Day 0	105 (31–387)	131 (53–349)	159 (66–374)	143 (31–387)	0.484
	Day 3	77 (22–347)[b]	145 (31–321)	165.5 (35–431)	145 (22–431)	0.048
Procalcitonin (ng/mL)	Day 0	19.3 (0.57–199.4)	6.4 (0.45–100)	5.8 (0.57–62.4)	7.5 (0.45–199.4)	0.160
	Day 3	16.8 (0.24–73.2)[ab]	2.5 (0.39–36.4)	4.1 (0.15–30.6)	5.0 (0.15–73.2)	0.013
CRP (mg/L)	Day 0	237 (16.7–425.9)	203 (82.1–552.6)	156.9 (49.1–420.1)	203.5 (16.7–552.6)	0.129
	Day 3	243 (54.3–424)	192 (20.6–1438)	173.2 (26.5–350)	193.7 (20.6–1438)	0.479
PT-INR	Day 0	1.46 (1.03–3.24)	1.33 (0.97–2.69)	1.26 (1.09–1.72)	1.30 (0.97–3.24)	0.292
	Day 3	1.35 (1.07–4.4)	1.29 (0.98–3.17)	1.27 (1.10–2.04)	1.31 (0.98–4.4)	0.110
aPTT (sec)	Day 0	32.7 (18.9–80.3)	34.7 (22.9–105)	32.5 (21–60.4)	33.6 (18.9–105)	0.543
	Day 3	36.5 (25.8–63.7)	32.5 (20.9–66.1)	30.7 (24.2–64.7)	33.5 (20.9–66.1)	0.123
Fibrinogen (mg/dL)	Day 0	504 (204–1134)[a]	592 (387–1200)[c]	455 (202–791)	521.5 (202–1200)	0.004
	Day 3	374 (103–751)[ab]	536 (377–1200)	529 (241–1115)	507 (103–1200)	<0.001
D-dimer (mg/L)	Day 0	7.1 (1.59–65)[ab]	2.02 (0.36–80)	2.86 (0.54–35.2)	2.96 (0.36–80)	0.001
	Day 3	7.2 (1.57–52)[a]	2.56 (0.37–25.45)[c]	5.27 (1.44–18.28)	3.78 (0.37–52)	<0.001

[a] p < 0.05 Decreased vs. Stable, [b] p < 0.05 Decreased vs. Increased, [c] p < 0.05 Stable vs. Increased

Discussion

Multiple laboratory parameters have been investigated for the early diagnosis and prognostic assessment of sepsis. With advancing technology, a variety of biomarkers have been utilized to predict coagulation disturbances, identify organ dysfunction, and estimate mortality. The importance of rapid diagnosis, early initiation of antimicrobial therapy, and fluid resuscitation has been highlighted repeatedly, most recently in the 2021 Surviving Sepsis Campaign guidelines (2).

Procalcitonin is one of the most frequently studied biomarkers in sepsis. A meta-analysis by Tan et al., including 495 septic and 895 non-septic patients, demonstrated that PCT has higher sensitivity and specificity compared with CRP (8). Similarly, Chen et al. showed in burn patients that PCT is valuable in the early detection of sepsis (9). Other studies have indicated that combining PCT with cytokines such as IL-6 and IL-8 improves diagnostic accuracy and prediction of organ dysfunction (10, 11).

Rowland et al. suggested that PCT should not be used alone but within an algorithm, emphasizing its role in reducing unnecessary antibiotic use (12). Suo et al. found that lactate, PCT, BNP, and APACHE II scores were elevated in septic patients and useful for early recognition (13). Likewise, Sridharan et al. reported that elevated PCT levels are more strongly associated with bacterial infections than with viral or fungal sepsis (14). In our study, higher PCT levels were observed in patients with higher SOFA scores and were linked with increased mortality.

Several pediatric and adult cohort studies have confirmed that PCT is superior to CRP in distinguishing bacterial from non-bacterial sepsis, though both biomarkers demonstrate moderate accuracy and should ideally be used in combination (15-17). In our analysis, decreased fibrinogen levels were associated with increased PCT values and higher SOFA scores, suggesting a link between coagulation abnormalities and systemic inflammation.

CRP has also been widely studied as a marker of sepsis severity and treatment response. Póvoa et al. reported that daily CRP monitoring after initiation of antibiotics is valuable, with a decline in CRP during the first five days correlating with prognosis (18). Other study has demonstrated that CRP trends are useful in community-acquired pneumonia and that a 50% reduction is associated with shorter hospital stay (19). In our results, patients with rising CRP levels had poorer outcomes and higher mortality compared with those without CRP elevation.

Coagulation parameters have also been investigated as prognostic indicators. Although another study has suggested that aPTT wave analysis may be useful in distinguishing sepsis from SIRS (20), our data did not demonstrate significant differences in aPTT. Similarly, INR has been proposed as a screening tool for non-pulmonary sepsis (21), but in our cohort fibrinogen levels were not significantly associated with INR or aPTT values.

The SOFA score remains one of the most validated prognostic tools in sepsis. Previous large-scale studies have shown that increases of ≥2 points are more strongly associated with mortality compared to SIRS or qSOFA criteria (22, 23). In line with these findings, we observed higher SOFA scores in patients with decreased fibrinogen levels, and thes(24) e patients also exhibited higher mortality. Likewise, higher ISTH scores were linked to increased mortality, consistent with previous reports (25).

Fibrinogen has been emphasized as a key biomarker in sepsis and DIC. Several studies have shown that low fibrinogen levels are associated with higher ISTH scores and increased mortality (4, 5, 26-29). In our study, decreased fibrinogen levels were closely associated with increased mortality, and this reduction coincided with changes in CRP, WBC, platelet, D-dimer, and PCT values.

Limitations

This study has several limitations. First, its retrospective and single-center design may limit the generalizability of the findings. Second, the relatively small sample size may have reduced the statistical power to detect weaker associations. Third, although we evaluated several commonly used biomarkers, other potentially relevant parameters such as lactate or interleukin levels were not included. Finally, as the study relied on electronic medical records, missing or incomplete data may have introduced bias.

Conclusion

In this study, a decreasing fibrinogen trend was associated with higher disease severity scores and increased mortality in patients with sepsis. Patients with reduced fibrinogen levels exhibited higher SOFA and ISTH scores and a significantly higher mortality rate compared with those with stable or increasing fibrinogen levels.

Conflict of interest

The authors declare no conflict of interest.

Financial disclosure

The authors received no financial support for this study.

Statement of ethical approval

This study was approved by ethical Committee of Health Science University İstanbul Kanuni Sultan Süleyman Education and Training Hospital on 08/02/2023 with approval number 2023.02.7.

Informed consent

Written and verbal informed consent was obtained from all participants prior to data collection.

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