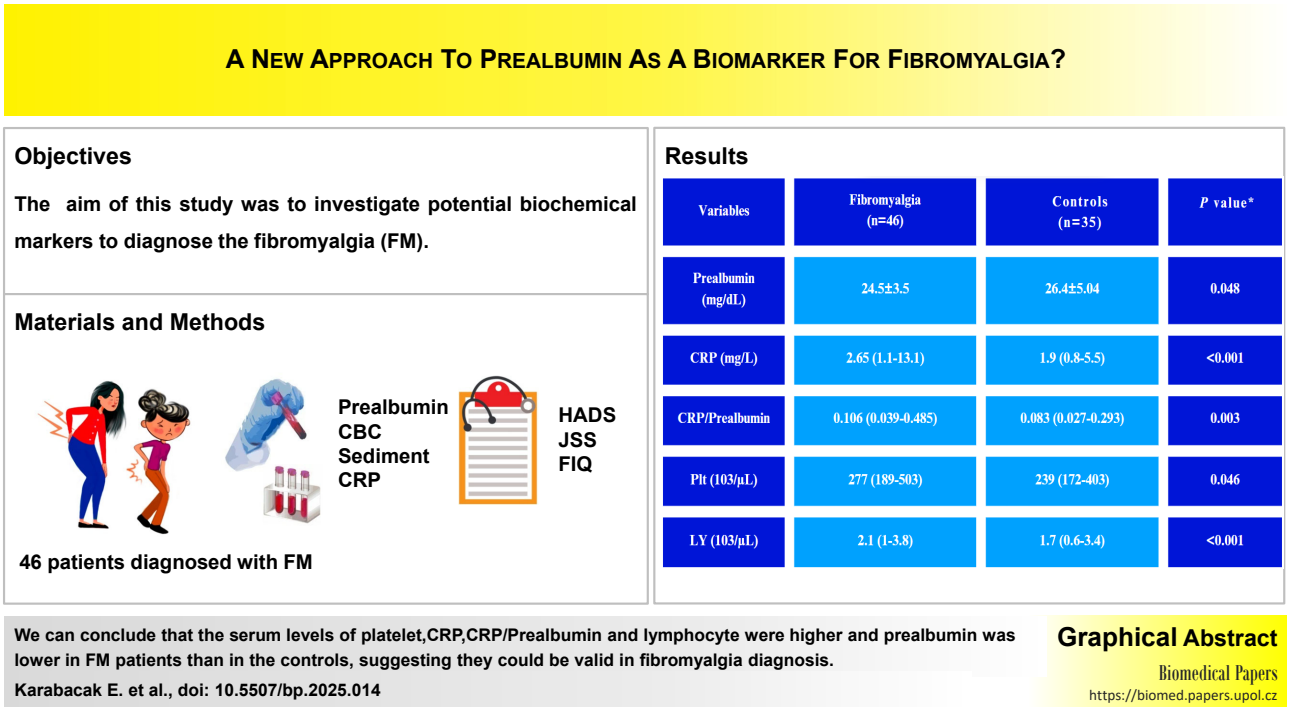
# A new approach to prealbumin as a biomarker for fibromyalgia?

Elif Karabacak[1], Muhtesem E. Yayla[2], Gulsah Y. Ozturk[3] , Bahadır Ozelbaykal[4]

**Aims.** Fibromyalgia (FM) is a chronic, widespread musculoskeletal disease that is usually accompanied by hyperalgesia, fatigue, sleep disturbance and depression. Although the etiopathogenesis of this syndrome is unclear, it is presumed to have an inflammatory basis. There are currently no laboratory markers available to diagnose the condition. The aim of this study was to investigate potential biochemical markers that would prove to be valid, simple, routinely used, quickly and cheaply studied and obtainable in blood count tests.
**Methods.** 46 patients diagnosed with FM according to ACR (American College of Rheumatology) 2010 diagnostic criteria and 35 patients as a healthy control group were included in the study. Prealbumin, complete blood count, sediment and C-reactive protein (CRP) values of FM and control group patients were examined. Additionally, Hospital Anxiety and Depression Scale, Jenkins Sleep Scale and the Fibromyalgia Impact Questionnaire (FIQ) were administered to patients diagnosed with FM.
**Results.** There was a significant difference between fibromyalgia patients and control groups in terms of prealbumin, platelet, CRP, CRP/prealbumin and lymphocyte parameters ($P$=0.048, $P$=0.046, $P$<0.001, $P$=0.003 and $P$<0.001, respectively). Only a weak positive correlation was found between CRP and FIQ ($r_s$ =0.309, $P$=0.037, CI=0.012–0.556).
**Conclusion.** The serum levels of some tested markers, including platelets, CRP, CRP/prealbumin and lymphocytes, were significantly higher and prealbumin was lower in patients with FM than in the control group, suggesting they could be valid in fibromyalgia diagnosis. The CRP level may be informative about the severity of the FM and it may play a role in the inflammation possibly underlying the pathogenesis of FM.




**Key words:** CRP, CRP/prealbumin, lymphocyte, platelet, prealbumin

Received: December 5, 2024; Revised: March 14, 2025; Accepted: April 24, 2025; Available online: May 16, 2025
https://doi.org/10.5507/bp.2025.014


[1]*Department of Pharmacology, Faculty of Pharmacy, Duzce University, Duzce, Turkey*
[2]*Family Medicine Department, Adana Medicine Faculty, Health Science University, Adana, Turkey*
[3]*Department of Physical Medicine and Rehabilitation, Adana Medicine Faculty, Health Science University, Adana, Turkey*
[4]*Ophthalmology Clinics, Adana City Training and Researching Hospital, Adana, Turkey*
*Corresponding author: Elif Karabacak, e-mail: elifkarabacak2010@hotmail.com*

## INTRODUCTION

Fibromyalgia syndrome (FM) is a chronic widespread musculoskeletal disease in which, in addition to hyperalgesia and allodynia, comorbidities such as fatigue, stiffness, sleep disturbance, depression, and anxiety are frequently observed. Its prevalence in the population is around 2–8%, and it is observed more frequently in women than in men, with a rate of 80–96% (ref.[1,2]). Genetic predisposition is an important etiological factor, and family members of patients with FM are known to be at higher risk for this disease[3]. However, the etiopathogenesis has not been sufficiently elucidated. It is thought that the basis of the widespread pain in FM is functional changes in pain pathways, neuroendocrine disorders and impaired sensory information processing in the central nervous system[4].

Studies have shown that patients with fibromyalgia are under oxidative stress and that inflammatory markers such as interleukins and C-reactive protein (CRP), a positive acute phase reactant, are higher in fibromyalgia patients than in the normal population[2,5].

Prealbumin, a negative acute phase protein, is a low-weight plasma protein and its normal plasma level is around 17–42 mg/dL. In case of inflammation, prealbumin synthesis in the liver is suppressed[6,7]. For this reason, it is speculated that the CRP/Prealbumin ratio may be a viable marker of inflammation[8]. One study showed that the CRP/Prealbumin ratio was higher in patients with rheumatoid arthritis, an inflammatory disease, than in healthy controls, and it was concluded that the CRP/Prealbumin ratio could be a useful inflammatory index in predicting disease and in prognosis[9].

While laboratory markers are used in cases of inflammatory diseases such as rheumatoid arthritis and ankylosing spondylitis, diagnosis can only be made by anamnesis and clinical examination due to the lack of laboratory markers to support the diagnosis of FM. Diagnostic criteria are largely based on the clinician's experience, which can lead to diagnostic inconsistencies. It is clear that research is needed to find biochemical biomarkers and evaluate their potential clinical value[2,4,5].

It is known that CRP is an acute phase reactant and a nonspecific marker used in the evaluation of systemic inflammation[5]. While this marker is frequently included in FM diagnostic studies, the relationship of CRP with FM has not been clearly determined. It has been reported that the newly introduced hs-CRP/Prealbumin ratio reflects the patient's inflammatory status better than hs-CRP or prealbumin alone[8].

In the studies conducted to date, none has been found to examine the relationship of prealbumin and CRP/prealbumin ratio to FM and its symptoms. In this study, we hypothesized that some biochemical markers found in FM patients could be informative for purposes of diagnosis and determining symptom severity. For this reason, we investigated selected physiological variables in FM patients, such as prealbumin, neutrophil, lymphocyte, platelet, CRP, CRP/prealbumin, and compared them with healthy controls. We aimed to evaluate the relationship between sleep disturbance, anxiety and depression levels and these parameters in FM patients.

## MATERIALS AND METHODS

Patients over the age of 18, who were regularly followed up with a diagnosis of fibromyalgia at the Physical Therapy and Rehabilitation Polyclinic of Adana City Training and Research Hospital and who applied between 20.01.2024 and 20.04.2024, were included in our study. Pregnant women, breastfeeding women, regular smokers and alcohol users, those with a history of cancer, diabetes mellitus, chronic renal failure, inflammatory rheumatic disease, hypothyroidism and those with a body mass index of 40 kg/m$^2$ and above were excluded from the study. Before the research, patients were informed about the purpose and content of the study. Written consent was obtained from patients who voluntarily agreed to participate in the study. The patients were divided into 2 groups: FM (n=46) and control group (n=35). Prealbumin, CRP, leukocyte, platelet, neutrophil, eosinophil, RDW, MPV values of both groups were examined. In order to evaluate the relationship between these values and comorbid symptoms in the FM group, the Fibromyalgia Impact Questionnaire (FIQ), Jenkins Sleep Scale (JUS), Hospital Anxiety Depression Scales (HADS) were filled out by the same physical therapy and rehabilitation specialist physician.

### Scales used

Hospital Anxiety and Depression Scale:

Hospital Anxiety and Depression Scale (HADS): Developed by Zigmond and Snaith, it is a scale consisting of a total of 14 questions that determine the level of anxiety and depression in the patient, with odd numbers representing anxiety (7 questions) and even numbers representing depression (7 questions). Each question is worth 0–3 points; 0–7 points are considered normal, 8–10 points are considered borderline, and 11 and above points are considered abnormal[10]. The Turkish validity and reliability of the four-point Likert scale scale was conducted by Aydemir and Koroglu[11].

Jenkins Sleep Scale:

Jenkins Sleep Scale (JSS) is a scale consisting of 4 questions developed by Jenkins et al. to evaluate the sleep quality of patients in the last month. It consists of 4 questions asking about sleep problems in the last month. Each question is between 0–5 points and consists of a total of 20 points. It is understood that the higher the score the lower is the person's sleep quality[12]. A Turkish validity and reliability study was conducted by Duruoz et al. in patients with rheumatoid arthritis[13].

### Fibromyalgia impact questionnaire

The Fibromyalgia impact questionnaire (FIQ) is a scale that evaluates the health status of fibromyalgia patients. While the first item consisting of 11 Likert-type

questions on daily life activities, the other items question incapacity, pain, fatigue, stiffness, sleep, anxiety and depression. It is scored between 0 and 100, with an increase in score with greater symptom severity[14]. The validity and reliability study was conducted by Sarmer et al.[15].

**Statistical analysis**

Statistical analyses were carried out on the SPSS 27 software (SPSS Inc, Chicago, IL, USA). The Chi-Square was used to test the differences between categorical variables. The normality of the data was tested using the Shapiro-Wilk test, independent Student's t tests and Mann-Whitnet U tests were used for the analysis accordingly. Pearson and Spearman correlation analysis were used to determine correlations between two variable. NCSS 2024 software was used for receiver operating characteristic (ROC) analysis. Cut-off value was determined according to the Youden index. Significant *P* value was considered as $P<0.05$.

## RESULTS

This study consisted of 81 individuals including, 46 FM patients (95.7% women) and 35 healthy control (91.4% women). The mean age was 49.4±10.4 years in patients and 47.8±14.4 years in controls. No statistically significant difference was found between the two groups in terms of age and gender ($P=0.559$, $P=0.434$, respectively).

As shown in Table 1, the CRP level in the FM patients was 2.65 mg/L (1.1–13.1) and 1.9 mg/L (0.8–5.5) in normal individuals ($P<0.001$). Prealbumin level was significantly lower in the FM patients (24.5±3.5 mg/dL) than controls (26.4±5.04 mg/dL) (df=79, t=−2.007, $P=0.048$). Platelet level was significantly higher in the FM patients than controls ($P=0.046$). Also, Platelet levels were 277 $10^3$/μL (189–503) and 239 $10^3$/μL (172–403) in FM patients and controls, respectively. The lymphocyte level was 2.1 $10^3$/μL (1–3.8) in the FM patients and 1.7 $10^3$/μL (0.6–3.4) in the controls, and this value was also statisticaly significant ($P<0.001$). No significant difference was found between groups in terms of other variables.

ROC analyses of Prealbumin, CRP, CRP/Prealbumin, platelet and lymphocyte parameters are summarized in Table 2. Based on the results of the ROC analysis to differentiate FM patients from normal individuals, the highest AUC values were obtained in CRP and lymphocyte parameters (0.7326, 0.7432, respectively).

There was a weak positive correlation between the CRP and FIQ score (rs=0.309, $P=0.037$, CI=0.012–0.556). However other blood parameters were not correlated with questionnaires as shown in Table 3.

**Table 1.** Shows demographic characteristics of enrolled individuals and values of study and control group parameters.

| Variables | Fibromyalgia (n=46) | Controls (n=35) | *P** |
|---|---|---|---|
| Mean Age (years) | 49.4±10.4 | 47.8±14.4 | 0.559 |
| Sex, Female (n) | 44 (95.7%) | 32 (91.4%) | 0.434 |
| Prealbumin (mg/dL) | 24.5±3.5 | 26.4±5.04 | **0.048** |
| CRP (mg/L) | 2.65 (1.1–13.1) | 1.9 (0.8–5.5) | **<0.001** |
| CRP/prealbumin | 0.106 (0.039–0.485) | 0.083 (0.027–0.293) | **0.003** |
| Wbc ($10^3$/μL) | 7.13±2.2 | 7.15±1.71 | 0.963 |
| Plt ($10^3$/μL) | 277 (189–503) | 239 (172–403) | **0.046** |
| RDW (%) | 14.2 (11.8–27.9) | 13.7 (12.7–17.4) | 0.064 |
| MPV (fl) | 8.7 (6.8–11) | 9 (7.6–11.7) | 0.262 |
| NE ($10^3$/μL) | 4.51±1.66 | 4.52±1.66 | 0.967 |
| LY ($10^3$/μL) | 2.1 (1–3.8) | 1.7 (0.6–3.4) | **<0.001** |

CRP, Creactive protein; Wbc, White bloodcells; Plt, Platelets; RDW, Redcelldistrubitionwidth; MPV, Mean platelet volume; NE, Neutrophils; LY, Lymphocytes.
**P* value of Mann-Whitney U test and independent Student t test according to normality.

**Table 2.** Shows receiver operating characteristic (ROC) analysis of parameters.

| Variables | Cut off ($mm^2$) | Sens (%) | Spec (%) | Accur | YI | AUC | *P* | 95% CI | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Lower | Upper |
| Prealbumin | 24 | 67.35 | 45.71 | 0.583 | 0.207 | 0.5904 | 0.085 | 0.446 | 0.704 |
| CRP | 2.2 | 63 | 74.29 | 0.679 | 0.373 | 0.7326 | **<0.001** | 0.6 | 0.826 |
| CRP/Prealb | 0.09 | 71.43 | 54.29 | 0.6429 | 0.3429 | 0.6799 | **0.0016** | 0.5416 | 0.7823 |
| Plt | 258 | 69.39 | 62.86 | 0.666 | 0.3224 | 0.6233 | **0.025** | 0.4843 | 0.7316 |
| Ly | 2.1 | 65.2 | 82.86 | 0.7143 | 0.4612 | 0.7432 | **<0.001** | 0.607 | 0.837 |

CRP, Creactive protein; CRP/Prealb, ratio of Crp to Prealbumin; Plt, Platelets; LY, Lymphocytes; Sens, sensitivity; Spec, specificity; Accur, Accuracy; YI, Youden index; AUC; area under the curve.

## DISCUSSION

Although the pathophysiology of fibromyalgia is largely unknown, it is reported that immune-inflammatory pathways may be involved[16]. We aimed to determine whether these inflammatory markers are increased in FM patients. We were looking for inexpensive markers that were easily evaluated in clinical practice.

There are no reliable laboratory markers for FM disease activity or severity and FM is difficult to diagnose. However, recent studies have shown that inflammatory mechanisms may play a role in itse pathogenesis. Biochemical mediators of inflammation include cytokines and neurotransmitters; many of these have been found to be abnormal in FM patients[16]. As an indicator of inflammation in fibromyalgia, it has been reported that positive acute phase reactants increase and negative acute phase proteins decrease in fibromyalgia patients compared to healthy control[17]. CRP, a positive acute phase reactant, is widely used as a marker of systemic inflammation. Studies on patients with fibromyalgia show that there is no consensus on CRP values. While this value is significantly higher than the control group in some studies[2,18-20] there is a significant difference in some has not been seen[21]. In our study, the CRP level in the patient group was found to be significantly higher than the control group. One study showed that prealbumin, a negative acute phase reactant, was found to be significantly lower in inflammatory diseases such as ankylosing spondylitis compared to the control, as in our study[22]. In another study, the CRP/prealbumin ratio was found to be significantly higher in patients with rheumatoid arthritis, an inflammatory disease, compared to the control group, as in our study[23].

In our study, the lymphocyte value was found to be significantly higher than the control similar to another study conducted on 40 fibromyalgia patients[21]. However, in the same study, when platelet and CRP values were examined, no significance was observed between the two groups, whereas in our study of 46 fibromyalgia patients, a significance was found in both parameters compared to the control. In another study, CRP, lymphocyte and platelet levels were found to be significantly higher in patients with fibromyalgia compared to the control group, as in our study[2]. In other studies, the number of platelets was found to be significantly higher, as in our study[19,24].

In another study conducted on fibromyalgia patients, serum levels of inflammatory markers tested, including erythrocyte sedimentation rate (ESR), CRP, NLR,

**Table 3.** Shows correlation analysis of parametres.

| | FIQ | HADS-A | HADS-D | JSS |
|---|---|---|---|---|
| Prealbumin (mg/dL) | $r_P$=0.88<br>*P*=0.563<br>CI=−0.209–0.368 | $r_P$=0.273<br>*P*=0.66<br>CI=−0.021–0.520 | $r_P$=0.104<br>*P*=0.49<br>CI=−0.193–0.382 | $r_S$=0.203<br>*P*=0.175<br>CI=−0.101–0.473 |
| CRP (mg/L) | **$r_S$=0.309**<br>***P*=0.037**<br>**CI=0.012–0.556** | $r_S$=0.029<br>*P*=0.849<br>CI=−0.272–0.324 | $r_S$=−0.104<br>*P*=0.490<br>CI=−0.391– 0.200 | $r_S$=0.66<br>*P*=0.662<br>CI=−0.237–0.358 |
| CRP/prealbumin | $r_S$=0.246<br>*P*=0.1<br>CI=−0.057–0.507 | $r_S$=−0.83<br>*P*=0.585<br>CI=−0.372–0.221 | $r_S$=−0.171<br>*P*=0.255<br>CI=−0.447–0.134 | $r_S$=0.026<br>*P*=0.863<br>CI=−0.274–0.322 |
| Wbc (103/μL) | $r_P$=0.153<br>*P*=0.311<br>CI=−0.146–0.423 | $r_P$=0.202<br>*P*=0.178<br>CI=−0.096–0.463 | $r_P$=0.229<br>*P*=0.126<br>CI=−0.068–0.485 | $r_S$=0.084<br>*P*=0.580<br>CI=−0.22–0.373 |
| Plt (103/μL) | $r_S$=−0.002<br>*P*=0.988<br>CI=−0.300–0.296 | $r_S$=0.051<br>*P*=0.735<br>CI=−0.251–0.344 | $r_S$=0.011<br>*P*=0.942<br>CI=−0.288–0.308 | $r_S$=0.034<br>*P*=0.821<br>CI=−0.267–0.329 |
| RDW (%) | $r_S$=0.119<br>*P*=0.433<br>CI=−0.186–0.403 | $r_S$=0.01<br>*P*=0.945<br>CI=−0.289–0.308 | $r_S$=0.206<br>*P*=0.17<br>CI=−0.099–0.475 | $r_S$=0.206<br>*P*=0.17<br>CI=−0.099–0.475 |
| MPV (fl) | $r_P$ = −0.029<br>*P*=0.849<br>CI=−0.316–0.264 | $r_P$ =−0.194<br>*P*=0.196<br>CI=−0.457–0.104 | $r_P$=−0.121<br>*P*=0.423<br>CI=−0.396–0.177 | $r_S$=−0.074<br>*P*=0.623<br>CI=−0.365–0.229 |
| NE ($10^3$/μL) | $r_P$ =0.226<br>*P*=0.132<br>CI=−0.072–0.482 | $r_P$ =0.175<br>*P*=0.244<br>CI=−0.123–0.441 | $r_P$ =0.16<br>*P*=0.289<br>CI=−0.139–0.429 | $r_S$=0.110<br>*P*=0.466<br>CI=−0.195–0.395 |
| LY ($10^3$/μL) | $r_S$=0.014<br>*P*=0.925<br>CI=−0.285–0.311 | $r_S$=0.144<br>*P*=0.339<br>CI=−0.161–0.424 | $r_S$=0.019<br>*P*=0.902<br>CI=−0.281–0.315 | $r_S$=−0.188<br>*P*=0.212<br>CI=−0.46–0.117 |

CRP, C-reactive protein; Wbc, White blood cells; Plt, Platelets; RDW, Red cell distribution width; MPV, Mean platelet volume; NE, Neutrophils; LY, Lymphocytes; FIQ, Fibromyalgia Impact Questionnaire; HADS-A, Hospital Anxiety and Depression Scale-assessing anxiety; HADS-D, Hospital Anxiety and Depression Scale-assessing depression; JSS, Jenkins Sleep Scale.

There was a weak positive correlation between the CRP and FIQ score (rs=0.309, *P*=0.037, CI=0.012–0.556). However other blood parameters were not correlated with questionnaires as shown in Table 3.

and MPV, were higher in patients than in controls. Additionally, in this study, some of these markers, especially the acute phase reactants, were found to be positively associated with disease severity and depression scores[20], but in our study, no correlation was found between these markers and the questionnaire scores.

In our study, the higher CRP, lymphocyte, prealbumin and platelet levels compared to the control may be due to inflammation. This may indicate that inflammation is involved in the pathogenesis of fibromyalgia. The high platelet value in our study is also an indicator of a prothrombotic situation that may increase with the increasing inflammatory state in fibromyalgia patients. This is also supported by another study in which the prothrombotic state of patients with fibromyalgia was investigated. In this study, fibrinogen elevation and prothrombin time decreased along with increased platelet count[24].

In a study conducted on patients with fibromyalgia and overweight/obesity, it was observed that CRP levels increased and that this group was the only group with a weak correlation between CRP and FIQ scores. It has been reported that this finding may suggest that the two sources of inflammation in this patient group are fatty tissue and fibromyalgia itself[25]. Our study included patients who were not obese, of the blood parameters and the questionnaires, only a weak positive correlation was found between CRP and FIQ. It has been stated that inflammatory markers in the blood (e.g. tumor necrosis factor-α, CRP) increase in various pain conditions such as back pain, neck pain, fibromyalgia[26]. In one study, patients with high hsCRP were found to have higher FIQ scores. They were also found to have worse physical function and more pain than patients with normal hsCRP (ref.[27]). Systemic CRP levels have been reported to be associated with pain intensity and hyperalgesia in back and neck pain. It has also been noted that this suggests that inflammatory processes may play a role in the outcomes of common chronic pain conditions[26].

CRP level may be informative about the severity of the FM disease and its symptoms. On the other hand, no correlation was found between blood parameters and the other scores of the questionnaires.

## CONCLUSION

Recent studies show that inflammation may play a role in the pathogenesis of fibromyalgia. To our knowledge, our study is the first to evaluate CRP/prealbumin and prealbumin values in patients with Fibromyalgia. The markers evaluated in this study are simple, routinely used, quickly and cheaply studied and can be obtained in all complete blood count tests. Our study results suggest that the CRP, CRP/prealbumin, lymphocyte and platelet levels increase in FM and the prealbumin level decreases, which may indicate the role of inflammation in the pathogenesis of FM. It was concluded that the inflammatory markers identified in this study may be useful in facilitating the diagnosis of patients with Fibromyalgia.

**Author contributions:** EK, MEY, GYO, BO: collected the data, did the analysis, manuscript writing; BO; contributed analysis tools, performed the statistical analysis. EK: supervised All authors have read and agreed to the published version of the manuscript.

**Conflicts of interests:** The authors declare that they have no conflict of interest.

**Ethical approval:** This study was performed in line with the principles of the latest Declaration of Helsinki. Approval was granted by the Ethics Committee of Adana City Training and Research Hospital (Date: 18 Jan 2024 /No: 3118).

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