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Randomized Controlled Study on the Effect of Using a Vein Imaging Device During Blood Collection From Peripheral Veins on Application Duration, Procedure-Related Pain, and Satisfaction Level

Periferik Venlerden Kan Alma Sırasında Ven Görüntüleme Cihazı Kullanımının Uygulama Süresi, Prosedüre Bağlı Ağrı ve Memnuniyet Düzeyi Üzerindeki Etkisine İlişkin Randomize Kontrollü Çalışma

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ABSTRACT Objective: Vessel imaging devices can streamline vein finding and blood collection, enhancing patient comfort. This study aimed to the effect of using vessel imaging devices during blood collection on the patient's procedure-related pain, satisfaction level, and application duration. Material and Methods: The research used a randomized controlled design with 100 participants at an outpatient blood collection unit in a training and research hospital from April 1-15, 2020. Fifty participants were assigned to the application group, where a vascular imaging device was used during the procedure, while the control group of 50 participants underwent the traditional method. Data were collected using the patient identification form, A visual analog scale was used for the assessment of pain and satisfaction levels. In evaluating the research data, descriptive statistical analyses (number, percentage, mean, standard deviation), hypothesis tests (Mann-Whitney U and Kruskal-Wallis tests), and Kolmogorov-Smirnov test were used to analyze normal distribution. Results: The groups were compared for procedure-related outcomes. While overall distributions were similar (p>0.05), significant differences were found in education, age, and previous blood collection experience (p<0.001). The application group had shorter blood collection times (mean duration: 2.78±1.07; p=0.000) and lower procedurerelated pain (mean score: 1.69±1.93; p=0.001) than the control group. Additionally, the application group reported higher satisfaction levels (mean score: 9.46±0.94; p=0.031). Conclusion: It was observed that the use of a vascular imaging device for venous blood collection from peripheral veins reduced the application duration of blood collection and pain level and positively increased satisfaction compared to the control group.

ÖZET Amaç: Damar görüntüleme cihazları damar bulma ve kan alma işlemlerini kolaylaştırarak hasta konforunu artırabilir. Bu çalışmanın amacı, kan alma işlemi sırasında damar görüntüleme cihazlarının kullanılmasının hastanın işlemle ilgili ağrısı, memnuniyet düzeyi ve uygulama süresi üzerindeki etkisini araştırmaktır. Gereç ve Yöntemler: Araştırma, 1-15 Nisan 2020 tarihleri arasında bir eğitim ve araştırma hastanesindeki ayakta kan alma ünitesinde 100 katılımcı ile randomize kontrollü bir tasarım kullandı. Elli katılımcı, işlem sırasında bir vasküler görüntüleme cihazının kullanıldığı uygulama grubuna atanırken, 50 katılımcıdan oluşan kontrol grubuna geleneksel yöntem uygulandı. Veriler hasta tanımlama formu kullanılarak toplanmış, ağrı ve memnuniyet düzeylerinin değerlendirilmesi için görsel analog ölçek kullanılmıştır. Araştırma verilerinin değerlendirilmesinde tanımlayıcı istatistiksel analizler (sayı, yüzde, ortalama, standart sapma), hipotez testleri (Mann-Whitney U ve Kruskal-Wallis testleri) ve normal dağılımı analiz etmek için Kolmogorov-Smirnov testi kullanılmıştır. Bulgular: Gruplar prosedürle ilgili sonuçlar açısından karşılaştırıldı. Genel dağılımlar benzer olmakla birlikte (p>0.05), eğitim, yaş ve daha önce kan alma deneyimi açısından anlamlı farklılıklar bulundu (p<0.001). Uygulama grubunun kan alma süresi kontrol grubuna göre daha kısa (ortalama süre: 2,78±1,07; p=0,000) ve işlemle ilişkili ağrıları (ortalama skor: 1,69±1,93; p=0,001) daha azdı. Ayrıca, uygulama grubu daha yüksek memnuniyet düzeyleri bildirmiştir (ortalama puan: 9,46±0,94; p=0,031). Sonuçlar: Periferik venlerden venöz kan alma işlemi için vasküler görüntüleme cihazı kullanımının, kontrol grubuna kıyasla kan alma işleminin uygulama süresini ve ağrı düzeyini azalttığı ve memnuniyeti olumlu yönde artırdığı görülmüştür.

Keywords: Blood collection; procedure related pain; satisfaction; vascular imaging; application duration Anahtar Kelimeler: Kan alma; işleme bağlı ağrı; memnuniyet; vasküler görüntüleme; uygulama süresi

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Laboratory tests are vital in making clinical decisions about the patient's health status. Determination of the diagnosis, and blood test is an important parameter in the implementation and maintenance of treatment of diseases. In the blood collection procedure applied for this purpose, the blood must be properly collected by using the correct technique. Blood collection is a nursing practice and accounts for 80% of invasive practices performed in hospitalized patients.^{1,2} Although blood collection is the most frequently applied invasive procedure, it is an application that causes the most pain and thus deterioration in comfort. Relieving and preventing pain is one of the basic nursing responsibilities. Even in basic applications such as establishing vascular access, the American Pain Association recommends minimizing pain and increasing the comfort of the patient by relieving them.³

The concept of comfort, expressed in the form of comfort that facilitates daily life, is based on the elimination of human needs in nursing. It is a concept that many nurse theorists (Roy, Kolcaba, Orlando, Watson, Patersor, Zderad) have included in their theories and it is seen as a part of quality nursing care.^{4,5} The pain experienced during the blood collection process negatively affects the comfort of the patient. Studies have shown that as pain level increases, the level of comfort decreases.^{5,6} Providing comfort and relieving pain are among the basic nursing requirements. Providing patient comfort during the blood collection process with a holistic approach will contribute positively to patient satisfaction.⁷ It is very important to use pharmacological and non-pharmacological methods in the management of pain, anxiety, and fear due to needle insertion attempts during the blood collection process. It is stated with moderate evidence that cooling and cooling methods, which are easy to use, provide a short-term effect, and reduce pain, anxiety, and fear during needle insertion attempts.8-10

During blood collection, healthcare professionals rely on traditional methods such as inspection and palpation skills as well as on anatomy knowledge for the detection of blood vessels. Although this method is fast and convenient, it is unsuccessful for non-superficial and small vessels. To increase the success rate in blood collection, various methods that facilitate access to the vascular system are recommended.¹¹ Spray, infrared light source ultrasound devices, and vascular imaging are some of these methods, and it is reported that new methods are more successful in blood collection than traditional ones.¹²⁻¹⁴ Thanks to the vessel imaging device (VID), the number of interventions, and the level of pain and fear reduced, and satisfaction and comfort increased. At the same time, the application duration of the procedure is shortened and, thus, enables the nurse to use their time more efficiently.^{15,16}

Patient satisfaction level and comfort are based on the extent patients' expectations are met as well as on their perception of the service provided in health institutions. Patient satisfaction level and comfort is an important indicator that reveals the success of the caregiver in meeting the values and expectations and shows the quality of care.^{17,18} However, the current technology seems to be limited in its application in clinics. The purpose of this study was to demonstrate the effect of using VID during the blood collection procedure.

MATERIAL AND METHODS

TYPE OF RESEARCH

This study was conducted in a randomized controlled trial design to determine the effect of using a vascular imaging device during blood collection on patient procedure-related pain, satisfaction level, and duration application (trial number taken from Clinical-Trials.gov identifier: NCT05678504).

THE HYPOTHESES OF THE RESEARCH

In this research, the following hypotheses were formed and the research process was organized.

H1: When vascular intervention is performed with an imaging device in adult patients, the **procedure-related pain level** is lower compared to the intervention performed without the device.

H2: When vascular intervention is performed with an imaging device in adult patients, the **procedure-related satisfaction level** is higher compared to the intervention performed without the device. H3: When vascular intervention is performed with an imaging device in adult patients, the **application duration** is shorter compared to the intervention performed without the device.

TIME AND PLACE OF RESEARCH

The study was conducted between 1-15 April 2022, in the blood collection unit of Sakarya Training and Research Hospital, outpatient services. The adult Blood Collection Unit is a unit with one room for six people and two rooms for two people, where patients are processed with their transaction numbers. A total of five nurses, one of whom is the responsible nurse, work in the unit. Nurses in the unit use inspection and palpation methods to visualize the vein during venous blood collection.

POPULATION AND SAMPLE OF THE RESEARCH

The population of the study consisted of adult patients who benefited from polyclinic services and applied to the Blood Collection Unit between the specified dates in a single center (n=504). With the G*Power (v3.1.7) (Heinrich Heine University Düsseldorf Universitätsstr. Düsseldorf, Germany) program applied to determine the sample of the study, the statistical power expressed as 1- β (β =Type II error probability) was calculated to be at least 90% and the error rate 5%, and a total of 100 people, who met the criteria for inclusion in the study, were included in the study. Sample; patients between the ages of 18 and 65, it is desired to take a peripheral blood collection, the integrity of the vein is intact, volunteered to participate in the study, did not have any pain complaints, did not take analgesics in the last 12 hours, could be contacted, did not have obesity, dehydration, peripheral edema, cancer diagnosis and did not need emergency intervention. A random number table was used to determine the application and control groups in the sample (Detailed information about randomization is stated in the application of the research section).

The flow chart of the Consolidated Standards of Reporting Trials 2010 regarding the population and sample of the research is shown in Figure 1.

DATA COLLECTION TOOLS

The data were collected with the patient identification form and visual analog scale (VAS). Patient identification form; It consisted of 11 questions in total, including individual characteristics [age, gender, marital status, educational status, body mass index (BMI), and previous blood collection experiences (complication status, use of analgesia)] created by the researchers.

VAS; In this study, VAS was used to measure both the procedure-related pain level and satisfaction level of patients. VAS is a scale that is often used for pain measurement and is scored between 0 and 10. The patient was asked to mark the amount of pain felt by the patient on a 10 cm ruler in such a way that the 0 cm scale was painless at one end and represented the most severe pain at the other end.¹⁹ To evaluate the satisfaction levels of the participants, a 10 cm ruler was used vertically, with dissatisfaction at one end and satisfaction at the other.⁶ Patients were asked to mark the point that best expressed their level of satisfaction. The markings made on the scales were measured with a ruler.

DEVISE USED IN RESEARCH

The VID, Vascularlite LEDX [(Veinlite, Sugar Land, Texas, USA)] brand, is portable and can display vessels approximately 10 mm below the skin, with its "C" shaped structure and bright LED lights, it helps to find the vasculature and fix the vessels during entry. It works by focusing 32 (24 orange and 8 red) LED lights located in the "C" shaped mouth part and placed at a certain angle, just under the skin. Due to their structure, blood vessels do not reflect orange light. In this way, while the tissue just under the skin is illuminated by 24 orange LEDs, the vessels passing through it appear dark. 8 red LEDs were used to facilitate vessel detection in darkly pigmented skin. The device can be switched on and off, only orange or red lights or both orange and red lights can be activated with the two buttons on the device.

The device comes into contact with the patient, but there is no risk of patient-to-patient infection as the changeable cases are replaced after each time of use. Also, using the device does not require a power source, nor does it need to be fixed to any surface or carrier foot. The rechargeable Li-Ion battery can operate for 160 hours. Moreover, the device does not emit any rays during operation; therefore, preventing long-term use-related eye fatigue (Figure 2, Figure 3).

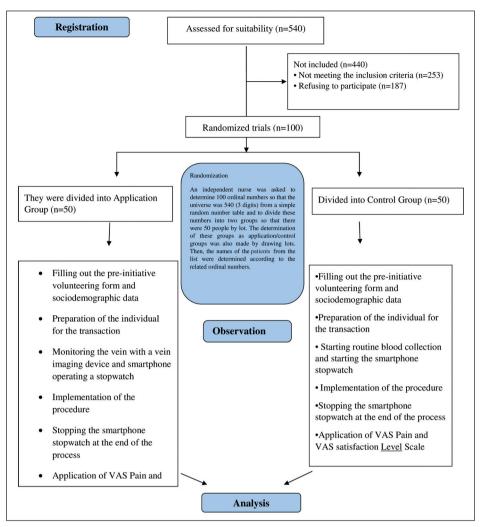


FIGURE 1: Research flow diagram. VAS: Visual analog scale.



FIGURE 2: Veinlite LEDX.

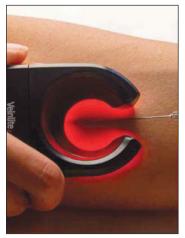


FIGURE 3: Veinlite LEDX-1.

IMPLEMENTATION OF THE RESEARCH

Randomization

An independent nurse was asked to determine 100 ordinal numbers so that the universe was 540 (3 digits) from a simple random number table and to divide these numbers into two groups so that there were 50 people. The determination of these groups as application/control groups was also done randomly. Then, the names of the patients from the list were determined according to the related ordinal numbers (Figure 1).

Application Group

The application of blood collection for the study was carried out by one of the study researchers who has 15 years of blood collection experience. Before the procedure, the pre-intervention patient identification form was completed. Then, the patient was given the appropriate position on the blood collection chair and preparation was made for the procedure application from the antecubial fossa area of the arm. After the tourniquet was applied to the patient, the blood collection area was cleaned with 70% alcohol. After waiting for drying, the procedure was performed. In the application group, the peripheral venous intervention area was imaged with VID Vascular Lite LEDX during the procedure and a 20 gauge needle was used while the intervention was performed. Before that, the smartphone's stopwatch program was started and the application duration was calculated. To measure procedure related the pain level and satisfaction level of the procedure, the VAS form was applied as two separate forms.

Control Group

The blood collection application of the control group was performed by the same researcher with 15 years of blood collection experience. Before the procedure, the pre-intervention patient identification form was completed. Then, the patient was given the appropriate position was given to the patient on the blood collection chair and preparation was made for the procedure from the antecubial fossa area of the arm. The procedure area of the person receiving the tourniquet was cleaned with 70% alcohol and allowed to dry. Before that, the smartphone's stopwatch program was started and the application duration was calculated. The control group was treated with a 20gauge needle without the use of a device. To measure procedure related the pain level and satisfaction level of the procedure, the VAS form was applied as two separate forms.

ETHICAL CONSIDERATIONS

Written permissions were obtained from the Interventional Ethics Committee of Sakarya University Faculty of Medicine, the Turkish Medicines and Medical Devices Agency (date: March 28, 2022, no: 2022-028), the relevant department, and the Hospital Management for the conduct of the research. The research was conducted by the principles of the Helsinki Declaration. For the study, the patients were informed about the purpose of the study, the procedures to be applied during the study, and the benefits of the study, and an informed consent form was obtained that they voluntarily participated in the study.

STATISTICAL ANALYSIS

SPSS version 22.0 for Windows (SPSS Inc., Chicago, IL, USA) was used in the evaluation of the obtained data. In all statistics, the significance value was evaluated as p<0.05 and the Kolmogorov-Smirnov test was used to homogeneity and the normal distribution.

The analysis of descriptive statistics (frequency, percentage, mean, standard deviation) and compare analysis groups (Mann-Whitney U and Kruskal-Wallis tests) were used in terms of variables, comparison analysis was used, and a p-value of less than 0.05 was accepted as statistically significant.

RESULTS

The findings of the study, which was carried out to determine the effect of using a vascular imaging device during the venous blood collection procedure, the sociodemographic characteristics of the patients, and their characteristics regarding the blood collection process are presented in Table 1 and Table 2 and Figure 4 and Figure 5.

In the study, the traditional method was used to identify the vein in 50 patients (50%) and the Vascularlite LEDX device was used in 50 patients (50%). Table 1 shows the sociodemographic characteristics

		Groups							
		Application group		Control group		Total			
Variables		n (50)	%	n (50)	%	n (100)	%	Test*	p value
Gender	Female	37	74	30	60	67	67	*1.628	0.202
	Male	13	26	20	40	33	33		
Marital status	Married	39	78	30	60	69	69	*2.992	0.084
	Single	11	22	20	40	31	31		
Educational status	Primary education	31	62	16	32	47	47	**13.364	0.001***
	High school-associate degree	12	24	11	22	23	23		
	Bachelor's degree	7	14	23	46	30	30		
Conducting bloodletting	I never mind	8	16	4	8	12	12	**8.220	0.042***
earlier	1-2 times	12	24	18	36	30	30		
	3-5 times	7	14	15	30	22	22		
	More than 5	23	46	13	26	36	36		
Complication status if done	Yes	12	24	17	34	29	29	*0.777	0.378
	No	38	76	33	66	71	71		
Using analgesia (Last 6 hours)	Yes	11	22	12	24	23	23	*0.000	1.000
	No	39	78	38	76	77	77		
Age (Mean SD)	je (Mean SD) 52.32±15.3		15.35	41.76±17.08		47.04±17.01		*792.500	0.002**
Body mass index (Mean SD)		27.80±	6.44	25.85	±5.09	26.83	+5.86	1040.500	0.149

*Mann-Whitney U test; **Kruskal-Wallis; ***p<0.05; SD: Standard deviation.

TABLE 2: Comparison of groups' characteristics related the blood collection during and after the procedure.									
Groups									
	Application group n (50)	Control group n (50)							
	X±SD	⊼±SD	Z	p value					
Application duration (as minute)	2.24±0.77	3.32±1.07	585.500	0.000*					
VAS-pain score	1.16±1.75	2.22±1.98	796.500	0.001*					
VAS-satisfaction level score	9.62±0.85	9.30±1.01	995.000	0.031*					

*Mann-Whitney U test p<0.05; SD: Standard deviation; VAS: Visual analog scale

and previous blood collection characteristics of individuals in groups. Although the patients had similar characteristics and homogeneous distribution in the application and control groups (p>0.05), it was observed that education (p=0.001), age (p=0.002), and previous blood collection (p=0.042) were not equally distributed between the groups (p<0.001) (Table 1).

Considering the duration of blood collection applied to the patients participating in the application and control groups; a statistically significant difference was found between the application (2.24 ± 0.77) and control (3.32 ± 1.07) groups (p=0.000). In the study, the shortening of the time was considered as

the success rate, since the blood collection attempt was made in one go for the entire sample, and it was seen in the analysis that the method used in blood collection had a marked effect on the success (**MU: 585.500; p=0.000) (Table 2).

The patients involved in the study were asked to evaluate the level of pain they felt during the application. While the mean scores of procedure-related pain levels were 1.16 ± 1.75 in the VID application group, it was 2.22 ± 1.98 in the control group, which was the traditional blood collection group, and there was a significant difference between the groups (MU: 796.500; p=0.001) (Table 2, Figure 4).

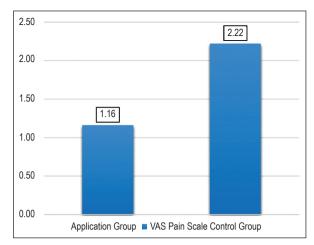


FIGURE 4: Mean scores of procedure-related pain levels of the groups. VAS: Visual analog scale.

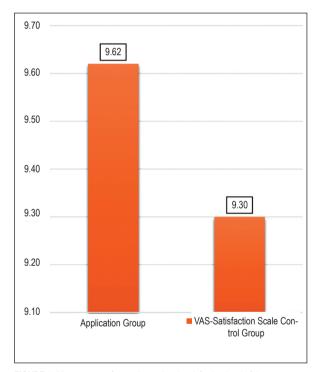


FIGURE 5: Mean scores of procedure-related satisfaction level of the groups. VAS: Visual analog scale.

Similarly, the mean scores of procedure-related satisfaction level of the patients were 9.62 ± 0.85 in the VID application group, whereas it was 9.30 ± 1.01 in the control group, which was the traditional blood collection group, and there was a significant difference between the groups (MU: 995.000; p=0.031) (Table 2, Figure 5).

DISCUSSION

Every day, around 500 million interventional procedures are performed on the vasculars in the world. The rate in the United States is more than 200 million a year. Although reaching the vasculature was between 95.2 and 97.3% in the first interventions, it was determined that the remaining 14 million blood collection procedures were successful in the second and subsequent trials.^{18,20,21} Pain is one of the undesirable experiences undergone by patients, which occurs due to any trauma, illness, or various necessary medical interventions. In earlier studies that examined pain levels during the blood collection procedure, different methods (ice, virtual reality glasses, distraction cards, etc.) have been employed to reduce pain, and studies proved the efficiency of these painalleviating methods.²²⁻²⁴ It is thought that VID will significantly reduce the anxiety and fear that both healthcare professionals and patients will experience during the procedure, especially in patients who have difficulty detecting vasculature. Hence, these interventional procedures performed on the vessels will become less painful for the patient.

In this study, the effect of the use of a vein imaging device during the blood collection process on patients in the application and control groups was investigated in terms of the pain and satisfaction levels of the patients as well as the application duration of the procedure. There was no statistically significant difference between the groups concerning variables such as gender, marital status, BMI, use of analgesia before blood collection, and complications after blood collection (p>0.05) (Table 1). The similarity of both groups in terms of these variables is a valuable criterion in evaluating the effectiveness of the Veinlite LEDX device. The notable difference between the groups in terms of mean age, educational status, and previous blood collection was not evaluated negatively as the study was conducted with randomization. It was observed that patients in the application group gave blood more than 5 times before the study, while patients in the control group gave blood 1-2 times. When the studies on the subject are examined, it has been noted that there are different results in the literature.^{16,24-29} It was

observed that the high number of blood collections in the application group did not affect the results obtained.

In the study, a statistically significant difference was found between the application and control groups in terms of the duration of application in the sense that the of the application group was shorter. This study's finding supports the H3 hypothesis. This aligns with earlier studies conducted with imaging devices in the literature in which the duration of application of the groups was shorter when the device was utilized.^{12,15,25,29} It was determined that an ultrasound device was used as VID and it was successful in blood collection compared to the traditional method.³⁰⁻³² It is thought that the main reason for the practicality of the use of the VID device is that it does not require as much experience as the use of ultrasound and also the differences in terms of imaging provided by the devices affect the practicality of use. In the visualization of the vein for blood collection, the imaging provided by the VID device is more comfortable, and material wastage is reduced compared to the imaging provided by ultrasound. It can be said that it is quite practical in preventing and reducing staff workload.

In the study, it was concluded that the pain levels of the group who underwent blood collection with the imaging device were low, and the satisfaction level of performing the procedure was high (Table 2, Figure 5). These findings support hypotheses H1 and H2. In the study of Guillon et al., it was found that the pain decreased with the vascular imaging technique, and the procedure tended to be more successful.³³ Likewise, in the study conducted by Demir, the pain level of those who underwent blood collection with a vein imaging device was found to be lower.¹⁵ In a similar vein, using an imaging device during the blood collection process from chemotherapy patients, Eren and Caliskan concluded that the satisfaction level of the patients who underwent blood collection with the device was high.³⁴ Similarly, in the study conducted by Zhang et al. on coronavirus disease-2019 patients, it was reported that the satisfaction level of the patients with the procedure performed with the infrared vascular imaging device was higher than the control group.²⁹ This finding of the research is supported by the findings in the literature and proves that the application performed with vascular imaging devices in a blood collection attempt is not only easy but also positive results are obtained for the patient.

LIMITATIONS

The fact that the study has two groups and that the groups are randomized increases its internal validity. In addition, the fact that the same nurse intervenes in both groups helps to control for external influences. However, the fact that the study was conducted in a single hospital limits the generalisability of the results. Although the patients in the application and control groups were homogeneous, one of the limitations of the study was that homogeneity was not achieved in some individual characteristics.

CONCLUSION

As a result of the study, it was determined that patient satisfaction level was high, the pain associated with the procedure was less and the application duration was shorter in the blood collection procedure performed with the vascular imaging device. Considering the density of outpatient blood collection units, it is recommended to use vein imaging devices in hospitals to reduce employee workload and increase patient satisfaction levels.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: Özlem Doğu; Design: Özlem Doğu, Esin Kelağalar; Control/Supervision: Özlem Doğu, Esin Kelağalar; Mustafa Altındiş; Data Collection and/or Processing: Esin Kelağalar, Özlem Doğu; Analysis and/or Interpretation: Özlem Doğu, Esin Kelağalar, Mustafa Altındiş; Literature Review: Özlem Doğu, Esin Kelağalar, Mustafa Altındiş; Writing the Article: Özlem Doğu, Esin Kelağalar, Mustafa Altındiş; Critical Review: Özlem Doğu, Mustafa Altındiş; References and Fundings: Özlem Doğu, Esin Kelağalar.

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