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Retrospective evaluation of pediatric trauma patients: a single-center experience of a tertiary pediatric intensive care unit

Pediatrik travma hastalarının retrospektif değerlendirilmesi: üçüncü basamak pediatrik yoğun bakım ünitesinin tek merkez deneyimi

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ABSTRACT

Aim: Due to the rapid development in pediatric critical care medicine, some past studies suggested that pediatric trauma patients have better outcomes such as lower mortality and lower length of hospital stay in the pediatric intensive care unit (PICU). In this study, we aim to describe the demographic, clinical features, mechanisms of injury, and outcomes of children hospitalized in our pediatric intensive care unit due to trauma.

Material and Method: We performed a retrospective evaluation of 60 pediatric trauma patients (between 0 and16 years of age) admitted to the PICU at University of Health Science, Sancaktepe Sehit Prof. Dr. İlhan Varank Training and Research Hospital from August 2020 to February 2022.

Results: A total of 60 pediatric trauma patients were followed up in our PICU. The median age of patients was 17 (0-724) months with a preponderance of male cases (n:38, 63.3%). The median duration of hospitalization in PICU was 6 (1-46) days. According to the trauma type, the majority of the injuries were falling from a height (n:37, 61.7%).

Conclusion: We would like to draw attention to the fact that head traumas due to falling were so common and also affect mortality. The lactate and the lactate/albumin ratio of patients who developed mortality were significantly higher. Although there are studies on the association of lactate/albumin ratio with mortality in critically ill pediatric patients, we could not find any data on this issue in pediatric trauma patients in the literature. Our study will contribute to the literature on the relationship between lactate/albumin ratio and mortality in pediatric trauma patients. We suggest that the relationship between lactate/albumin ratio and mortality should be investigated in pediatric trauma patients with larger case numbers.

Keywords: Pediatric intensive care unit, pediatric trauma, lactate/albumin ratio

ÖZ

Amaç: Pediatrik kritik bakım tıbbındaki hızlı gelişme nedeniyle, geçmişteki bazı araştırmalar, pediatrik travma hastalarının daha düşük mortalite ve daha kısa hastanede kalış süresi gibi daha iyi sonuçlara sahip olduğunu ileri sürmüştür. Bununla birlikte, çoğu gelişmekte olan ülkede, pediatrik travma merkezleri çok azdır veya hiç yoktur. Bu çalışmada travma nedeniyle çocuk yoğun bakım ünitemizde (ÇYBÜ) yatan çocukların demografik, klinik özellikleri, yaralanma mekanizmaları ve sonuçlarını tanımlamayı amaçladık.

Gereç ve Yöntem :Ağustos 2020 - Şubat 2022 tarihleri arasında Sağlık Bilimleri Üniversitesi, Sancaktepe Şehit Prof. Dr. İlhan Varank Eğitim ve Araştırma Hastanesi ÇYBÜ'ne başvuran 60 pediatrik travma hastası (0-16 yaş arası) retrospektif olarak değerlendirildi.

Bulgular :ÇYBB'mizde toplam 60 çocuk travma hastası takip edildi. Hastaların medyan yaşı 17 (0-724) aydı ve erkek olgular çoğunluktaydı (n:38, %63,3). ÇYBÜ'de medyan yatış süresi 6 (1-46) gündü. Travma tipine göre yaralanmanın büyük kısmı yüksekten düşme (n:37, %61,7) idi. Travmaya bağlı genel ölüm oranı %13.3 idi.

Sonuç: Düşmeye bağlı kafa travmalarının çok yaygın olduğuna ve mortaliteyi etkilediğine dikkat çekmek isteriz. Mortalite ile laktat, laktat/albümin oranı arasında anlamlı bir ilişki bulduk. Kritik hasta pediatrik hastalarda laktat/albümin oranının mortalite ile ilişkisine yönelik çalışmalar olmasına rağmen literatürde pediatrik travma hastalarında bu konuda herhangi bir veri bulamadık. Çalışmamız pediatrik travma hastalarında laktat/albümin oranı ile mortalite arasındaki ilişki ile ilgili literatüre katkı sağlayacaktır. Vaka sayısı fazla olan pediatrik travma hastalarında laktat/albümin oranı ile mortalite arasındaki ilişkinin araştırılmasını öneriyoruz.

Anahtar Kelimeler: Çocuk yoğun bakım ünitesi, çocuk travması, laktat/albümin oranı

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INTRODUCTION

Pediatric trauma is the leading cause of admission to the pediatric emergency departments (1). Blunt traumas are the most common injury in childhood and account for 85% of the cases (2). Injury takes an important place among the most common causes of death in children older than 1 year of age, and the majority of these deaths occur in developing countries (3). Mortality due to pediatric trauma was reported as 40% at the time of the accident, 30% in the early period, and 30% in the late period, respectively (2). While the mortality in the early period is due to hypoxia, hypovolemia, and severe head trauma, SIRS (Systemic Inflammatory Response Syndrome), MOFS (Multiple Organ Failure Syndrome), sepsis, and ARDS (Acute Respiratory Distress Syndrome) are the most common causes that increase mortality in the late period (2).

According to the American College of Surgeons National Trauma Databank 2014 data, 42% of pediatric trauma patients are admitted to an intensive care unit (4). In addition, head trauma ranks first among patients requiring intensive care hospitalization with a rate of 57%. Since there are significant physiological and anatomical differences in childhood compared to adult patients, susceptibility to trauma increases, injury mechanisms change, and there are differences in the evaluation/ treatment of pediatric trauma patients (2). Due to the rapid development in pediatric critical care medicine, some past studies suggested that pediatric trauma patients have better outcomes such as lower mortality and lower length of hospital stay by the treatment in the pediatric intensive care unit (5). However, in most developing countries, pediatric trauma centers are few or not present at all. On the other hand, it was reported that the outcomes of severely injured patients who were admitted to trauma centers were better compared to non-trauma centers (6).

Mechanisms and types of accidents also change depending on age. The most common causes of trauma in children are falling, in-vehicle or out-of-vehicle traffic accidents, bicycle accidents,water drowning, burns, and child abuse (7).

In this study, we aim to describe the demographics, clinical features, mechanisms of injury, and outcomes of children who were admitted to our pediatric intensive care unit (PICU) following trauma.

MATERIAL AND METHOD

The study was carried out with the permission of University of Health Science, Sancaktepe Şehit Prof. Dr. İlhan Varank Training and Research Hospital Scientific Researches Ethics Committee (Date: 15.06.2022, Decision No: E-46059653-020-552). This study was carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki Principles.

Study Population

We performed a retrospective evaluation of 60 pediatric trauma patients (between 0 and16 years of age) admitted to the PICU at University of Health Science, Sancaktepe Şehit Prof. Dr. İlhan Varank Training and Research Hospital from August 2020 to February 2022. Informed consent was obtained from all parents before hospitalization and during all procedures.

Patient Characteristics

Data was collected using a detailed form regarding the patient's age, gender, type of trauma, cause of trauma, length of stay in PICU, duration of mechanical ventilation, the requirement of surgical intervention, cranial CT findings, the requirement of the catheter, the requirement of transfusion, treatment options, treatment outcomes, and mortality. Lactate value in blood gas analysis and the serum albumin level on admission was recorded. Glasgow Coma Scale (GCS) is used to assess the level of consciousness and to predict the severity and early period of mortality due to neurological function disorders and is scored between 3 and 15 based on visual, verbal, and motor responses given to various types stimuli (8). Vasoactive Inotropic Score (VIS) is used to assess the amount of cardiovascular support required by trauma patients and includes dopamine, dobutamine, epinephrine, milrinone, vasopressin, and norepinephrine (9). For the calculation of the Pediatric Risk of Mortality III (PRISM III) Score, data for the following 16 variables were collected within 24 h of PICU admission: temperature, systolic blood pressure, heart rate, partial pressure of arterial oxygen (PaO_2), partial pressure of arterial carbon dioxide ($PaCO_2$), GCS), pupillary reaction, prothrombin time (PT) and activated partial thromboplastin time (APTT), serum creatinine, serum urea nitrogen, serum potassium, blood glucose, and serum bicarbonate levels, white blood cell and platelet counts (10).

The patients were defined as multisystem trauma if they had injuries including two or more organs in different cavities or damage to internal organs and the musculoskeletal system including the face and the pelvis.

Statistical Analysis

Statistical analyses were done by using SPSS statistical software for Windows, 20.0. Numbers, frequencies [%], ratio, medians, and standard deviation values were used in the descriptive statistics of the data. The distribution of variables was checked with the Kolmogorov Smirnov test. During the analysis of quantitative data t-tests and Mann-Whitney, u-tests were used. The $\chi 2$ test was used

to compare categorical variables, and the Fischer test was used when chi-square conditions could not be met. PRISM score and lactate/albumin ratio were further evaluated for their predictivity of mortality by ROC curve analysis. According to the estimated cut-off, PRISM score values and lactate/albumin ratio were transformed to binary variables. Consequently, odds ratios are calculated for observed frequencies.

RESULTS

We evaluated 60 pediatric trauma patients followed up in our PICU. The median age of patients was 17 (0-724) months with a preponderance of male cases (n:38, 63.3%). The median duration of hospitalization in PICU was 6 (1-46) days. While accidents (n:52, 86.7%) were the most common cause of trauma, it was followed by child neglect-abuse (n:6, 10%) and suicide (n:2, 3.3%). When injuries were evaluated, it was determined that most of them were falling from a height (n:37, 61.7%), vehicle accidents, cutting injuries, and drowning. Among 60 patients 33 (55%) required invasive mechanical ventilation, and 13 (21.7%) required non-invasive mechanical ventilation. The median duration of invasive mechanical ventilation was 2 (0-4) days. The median PRISM score of the patients was 7 (0-39). The mortality rate due to trauma was (n:8, 13.3%)(**Table 1**).

Table 1. Clinical features of trauma patients

Features (n=60)	
Age (months), median (min-max)	17 (0-724)
Sex (n,%)	
Male	38 (63.3)
Female	22 (36.7)
Total	60 (100)
Cause of trauma (n,%)	
Suicide	2 (3.3)
Accident	52 (86.7)
Neglect and abuse	6 (10.0)
Total	60 (100)
Type of trauma (n,%)	
Motor vehicle accident (vehicle occupant)	4 (6.7)
Motor vehicle accident (pedesterian)	14 (23.3)
Fall	37 (61.7)
Injury by a sharp object	1 (1.7)
Drowning	4 (6.7)
Total	60 (100)
Mortality (n,%)	
Yes	8 (13.3)
No	52 (86.7)
Total	60 (100)
Duration of Hospital Stay (day), median (min-max)	6 (1-46)
Duration of Invasive Mechanical Ventilation (day), median (min-max)	2 (0-46)
Duration non-invasiveive ventilation (day), median (min-max)	0 (0-10)
PRISM score, median (min-max)	7 (0-39)
VIS score, median (min-max)	0 (0-98)

PRISM III: Pediatric risk of mortality III Score, VIS: Vasoactive inotropic score

When our trauma patients were evaluated according to the affected body parts, most of the patients (n:32, 53,3 %) were in the head trauma group. There were 12 (20%) patients in the multisystem trauma group and 8 (13.3%) of them had head trauma. In 16 (26.7%) patients, there were signs of trauma in one of the body parts other than the head. While 24 of 60 patients had normal CT images, the most frequent abnormal cranial CT finding was subdural hemorrhage (n:14, 23.3%) and subarachnoid hemorrhage (n:10, 16.7%). Other radiological findings were epidural hemorrhage and cerebral edema. Ten patients (16,7%) required surgical intervention and the most common type of surgery in these patients was neurosurgery (n:9, 90%). One patient required orthopedic surgery in addition to neurosurgery. Mannitol was given to 5 (8.3%) patients in addition to 3% hypertonic saline due to cerebral edema (**Table 2**).

Table 2: Clinical Features of Trauma Patients

Features	
Surgical intervention (n,%)	
Yes	10 (16.7)
No	50 (83.3)
Total	60 (100)
Type of surgery (n,%)	
Multisystem	1 (10.0)
Cranial	8 (80.0)
Extracranial	1 (10.0)
Total	10 (100)
CT findings (n,%)	
Normal	24 (40.0)
Subdural hemorrhage	14 (23.3)
Subarachnoid hemorrhage	10 (16.7)
Epidural hemorrhage	6 (10.0)
Cerebral edema	6 (10.0)
Total	60 (100)
Transfusion (n,%)	
Yes	39 (65)
PRBC (n)	35
FFP (n)	34
PS (n)	5
No	21 (35)
Total	60 (100)
Mannitol use (n,%)	
Yes	5 (8.3)
No	55 (91.7)
Total	60 (100)
Sedative medication use (n,%)	
Use of 2 or more drugs	12 (30.8)
Single drug use	27 (69.2)
Total	39 (100)
Analgesic medication use (n,%)	
Continuous infusion	40 (66.7)
Intermittent	20 (33.3)
Total	
Catheter sites (n,%)	
Jugular	16 (48.5)
Femoral	16 (48.5)
Subclavian	1 (3.0)
Total	33 (100)

PRBC: Packed red blood cell, FFP: Fresh frozen plasma, PS: Platelet suspension

While the need for transfusion developed in approximately two-thirds of the patients, the total number of blood product replacements was 74. The most commonly administered blood product (35 times) was packed red blood cell (PRBC), followed by 34 times fresh frozen plasma (FPP) and 5 times platelet suspension (PS). In total, 39 (65%) patients were sedated. While single sedation was the most preferred sedation strategy for 27 (69.2%) patients, 12 (30.8%) patients required more than one sedative agent. Of the 60 patients, 40 (66.7%) patients required intravenous analgesic infusion, other patients received intermittent analgesic medication. Jugular (n:16, %48,5), femoral (n: 16, 48,5%), or subclavian (n:1, 3%) central venous catheters were inserted in 33 patients (**Table 2**).

Although there is not a significant difference, the majority of cases were falling from a height with 23 (62.2%) patients in the head trauma group and 8 (21.6%) patients in the multisystem trauma group, respectively (**Table 3**).

When all parameters were evaluated according to the affected system, there was a positive correlation between only lactate value in the brain and one other system (thorax, abdomen, locomotor, etc.) and one and more than one system. There was not a statistically significant difference in duration of invasive/non-invasive mechanical ventilation, duration of PICU stay, PRISM III score, VIS score, and mortality between patients according to the affected body part (**Table 3**).

The need for mechanical ventilation, the need for PRBC transfusion, PRISM score, and VIS score of patients who developed mortality were significantly higher. Also, the lactate/albumin ratio of patients who developed mortality was significantly higher (**Table 4**).

ROC analysis is used for PRISM score and lactate/albumin ratio. According to ROC analysis, cut-off values are found as 13.50 and 0.9853 respectively (**Figure 1**, **Figure 2**). Cases were classified as positive and negative referred to as estimated cut-off values by ROC curve analysis. It would be estimated that possibility of being positive in the lactate/albumin ratio is 38.50 times more than being negative in cases of death (OR=38.50 (95% CI: 4.154-356.83). However, we could not estimate any defined odds ratio for PRISM cut-off due to any case that resulted in death having negative values (**Table 4**).

Table3. Clinical characteristics of trauma patient according to the affected organ

Features	Affected Organ			P value
	Cranial (n=32)	Multisystem (n=12)	Other (n=16)	
Hospitalization day, median (min-max)	5 (1-46)	8 (2-21)	7 (1-25)	0.376
Invasive mechanical ventilation (n,%)				0.081
Yes (n=33)	20 (60.6)	8 (24.2)	5 (15.2)	
No (n=27)	12 (44.4)	4 (14.8)	11 (40.7)	
Noninvasive mechanical ventilation (n,%)				0.841
Yes (n=13)	8 (61.5)	2 (15.4)	3 (23.1)	
No (n=47)	24 (51.1)	10 (21.3)	13 (27.7)	
Cause of trauma (n,%)				0.672
Suicide (n=2)	1 (50)	0 (0)	1 (50)	
Accident (n=52)	29 (55.8)	10 (19.2)	13 (25)	
Neglect and abuse (n=6)	2 (33.3)	2 (33.3)	2 (33.3)	
Type of trauma (n,%)				0.053
Motor vehicle accident (vehicle occupant) (n=4)	2 (50)	2 (50)	0 (0)	
Motor vehicle accident (pedesterian) (n=14)	5 (35.7)	2 (14.3)	7 (50)	
Fall (n=37)	23 (62.2)	8 (21.6)	6 (16.2)	
Injury of sharp object (n=1)	1 (100)	0 (0)	0 (0)	
Drowning (n=4)	1 (25)	0 (0)	3 (75)	
Mortality (n,%)				0.111
Yes (n=8)	5 (62.5)	3 (37.5)	0 (0)	
No (n=52)	27 (51.9)	9 (17.3)	16 (30.8)	
PRISM score, median (min-max)	8 (0-32)	8 (0-39)	4 (0-21)	0.094
VIS score, median (min-max)	0 (0-98)	0 (0-35)	0 (0-6)	0.440
Lactate, median (min-max)	1.95 (0.4-19.0)	1.7 (0.7-9.4)	0.95 (0.56-3.30)	0.017 *

PRISM III: Pediatric Risk of Mortality III Score, VIS: Vasoactive Inotropic Score *Significance for lactate value is between cranial and other and multisystem and other

Table 4. Comparison of survivors and non-survivors

Features	Mortality			p value	OR (95%CI)
	No (n=52)	Yes (n=8)	Total		
Hospitalization day, median (min-max)	6 (1-46)	2 (2-21)	8	0.076	N/A
Mechanical ventilation (n,%)				0.008	N/A
Yes (n=34)	26 (76.5)	8 (23.5)	34 26		
No (n=26)	26 (100)	0 (0)			
PRBC transfusion (n,%)				0.016	N/A
Yes (n=35)	27 (77.1)	8 (22.9)	35		
No (n=25)	25 (100)	0 (0)	25		
GKS, median (min-max)	12 (3-15)	3 (3-4)	15	<0.001	N/A
PRISM score, median (min-max)	6 (0-22)	24 (15-39)	30	<0.001	N/A
VIS score, median (min-max)	0 (0-30)	20 (0-98)	20	<0.001	N/A
PRISM score				<0.001	N/A
<13.50	44	0	44		
≥13.50	7	7	14		
Total	51	7	58		
Laboratory Findings				0.002	N/A
Lactate, median (min-max)	1.5 (0.4-9.4)	3.20 (1.7-9.0)			
Lactate/albumin ratio, median (min-max)	0.38 (0.17-2.30)	1.04 (0.54-0.42)		<0.001	38.50 (4.154-356.83)
Lactate/albumin ratio				<0.001	38.50 (4.154-356.83)
<0,985	44	1	45		
≥0,985	8	7	15		
Total	52	8	60		

PRBC: Packed red blood cell, GCS: Glasgow Coma Scale, PRISM III: Pediatric Risk of Mortality III Score, VIS: Vasoactive Inotropic Score, OR: Odds ratio

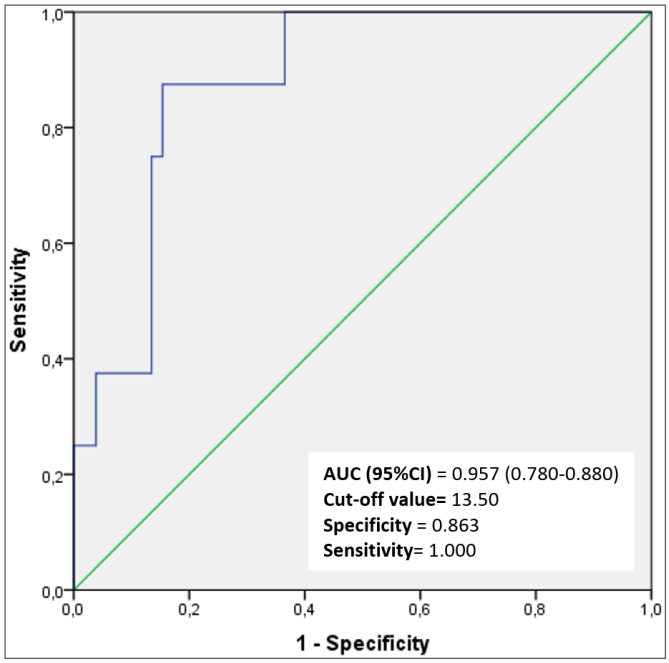

Figure 1. ROC Curve for the lactate/albümin ratio

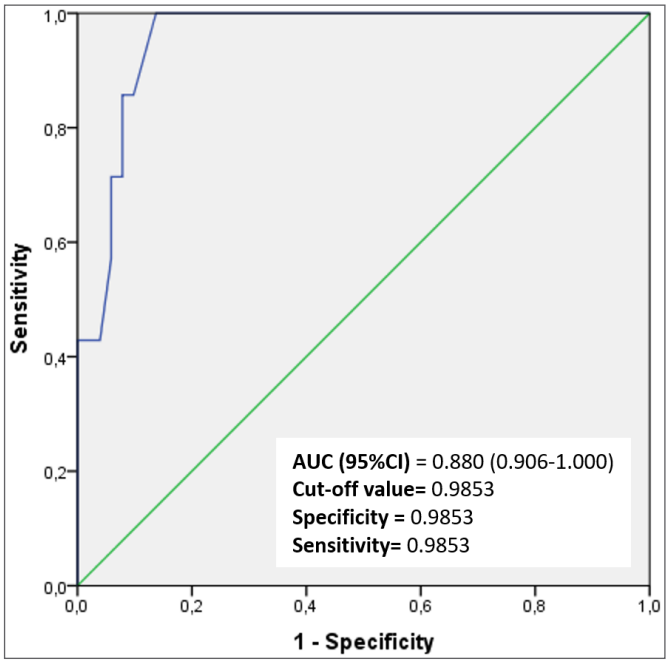

Figure 2. ROC Curve for PRISM score value

DISCUSSION

There are different results in the literature regarding the median age of pediatric trauma patients. Previously, Densmore et al. (5) reported that the median age of pediatric trauma patients was 12.2±6.2 years and in another study, Voth et al. (11) found that the median age of the pediatric patients was 8 years. In a study from Turkey, it was seen that the mean age of the patient was 77 months (3). Compared with other studies, a study in Brazil has a closer resultin which the mean age was 33 months (12). In some studies, the average age is reported to be between 33 and 77 months and boys were more frequently injured than girls (3,7,12,14). The main findings of this our study were such as; the median age of our pediatric patients admitted to the PICU was 17 months and most of them were male. In this study, boys were more frequently injured than girls as reported in other studies (1,3,7,13,14).However, the median age in our patients was found to be lower compared to previous studies. In our opinion, this result is related to the fact that younger children are more exposed to home accidents such as falling from a height due to the longer stay at home during the pandemic.

In the literature, there are studies in which the length of hospital stay varies between 4 and 11 days (3,13). In accordance with these results, the median duration of PICU stays in our study.

The mechanism of injury can differ by country related to their high or low-middle income. In the USA, motor vehicle accidents had been found as the most common mechanism of injury in injury-related deaths among 1–20 years aged patients, while the study by Herbert et al. (15) from South Africa which is covering 10 years, found that falls were among the most frequent mechanism type of injury compromising 39.8% (3). Studies from Turkey generally demonstrated that falling cases are more common than other trauma types which are similar to this study (1).

Although previous studies reported a wide range of mortality rates, from 3% to 17%, in general opinion, trauma patients have the highest mortality and morbidity among patients admitted to the PICU (3,13,16,17). The mortality rate in this study was 13.3 %. We attribute the high mortality rate in our study to the fact that the majority of our trauma patients were caused by head trauma, which is the highest-risk patient group.

PRISM score is one of the main indicators used in the pediatric intensive care unit (12,18). In a study performed in Sao Paulo, 54 (15%) of 359 patients died. The median mortality-associated PRISM score in dead patients was higher (median 8 points; min4-max14) compared to a lower score in patients who survived (median 7; min 3-max 12) (12). Similarly, in our study, 8 (3.3 %) of 60 patients died and the PRISM score was higher (median 7; min 0-max 39). In the light of this result, we think that the PRISM score is quite reliable in predicting mortality in trauma patients.

Head trauma is the most common form of pediatric trauma and is the most common cause of trauma-related mortality and morbidity (19,20). Mayer et al. (21) revealed that head trauma is the most common type of injury (78.8%) in the pediatric population. A study from Turkey reported that 73.5% of the patients had head trauma (19). In another study from our country by Emeksiz et al. (22), it was shown that the most common cause of trauma was falling and all the patients who followed up had head trauma. In our study, 66.6% of trauma patients had head trauma and subdural hemorrhage was the most common finding in CT. As in previous studies, we would like to draw attention to the fact that head trauma due to falling is very common and affects mortality.

Transfusion is an important part of trauma resuscitation (23). Hassan et al. (23) compare the characteristics and outcomes of children admitted to the ICU after traumatic injury, who did or did not receive PRBC transfusions. Transfused patients had greater PICU length of stay (LOS) and mortality. PRBC-transfused patients had a significantly greater requirement for mechanical ventilation and a longer duration of mechanical ventilation. We found that all 8 patients who can not survive, received PRBC transfusions and the transfusion requirement was significantly higher when compared to the survivor patients. Also, the duration of mechanical ventilation was significantly higher in non-survivor patients.

Many predictive biomarkers such as lactate (24,25) and albümin (26) have been developed to assess the prognosis and mortality in critically ill children. Lately, it was reported that the combination of lactate and albumin is a better predictor of mortality in critically ill patients (27-29). As each of the two parameters independently predicts mortality, a combination of both was meant to further increase the predictive value (29). In an adult trauma study, lactate and glucose levels were significantly higher, on the other hand, albumin and PaO_2/FiO_2 levels were significantly lower in non-survivor patients (30). Another adult trauma study showed that non-survivor patients had significantly higher MV duration, ICU length of stay, CRP and lactate level, higher lactate/albumin ratio, and significantly lower albumin level compared to surviving patients (31). But there are only a few studies that examined the lactate/albümin ratio in critically ill children. Most of the pediatric studies were designed to evaluate the prognostic value of the serum lactate/albumin ratio in septic patients. However, we could not find any study in the literature on the relationship between lactate/albumin ratio and mortality in pediatric trauma patients. Previously it was evaluated that the mortality in pediatric septic shock patients with underlying chronic disease was %26.7, and the albumin level was lower in non-survivors than in survivors. Additionally, the lactate/albumin ratio was 0.9±0.8 in survivors and 3.2±2.4 in non-survivors ($p<0.001$) (32). In our study, the lactate/albumin ratio of patients who developed mortality was significantly higher andthe lactate/albumin ratio above the cut-off value of 0.880 increased the mortality rate 38.50 times. In our opinion, this study will contribute to the literature on the relationship between lactate/albumin ratio and mortality in pediatric trauma patients.

CONCLUSION

In our opinion, our data will contribute to the literature since there is limited data in the literature regarding the follow-up of pediatric trauma patients in the PICU. We suggest that the relationship between lactate/albumin ratio and mortality should be investigated in pediatric trauma patients.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of University of Health Science, Prof. İlhan Varank Sancaktepe Training and Research Hospital Scientific Researches Ethics Committee (Date: 15.06.2022, Decision No: E-46059653-020-552).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper and that they have approved the final version

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