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Editorial
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Addressing the Primary Causes of Door-in to Door-out Time Delay in ST-elevation Myocardial Infarction: Can They be Minimised

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Keywords: Door-in, door-out, myocardial infarction, time, ST-elevation, reperfusion

In the realm of emergency medicine, every minute counts, particularly when it comes to managing acute conditions like ST-elevation myocardial infarction (STEMI). Rapid identification and early treatment of acute STEMI are critical in reducing morbidity and mortality. Early reperfusion has shown to improve overall outcomes in patients with STEMI (1).

Various guidelines and treatment strategies aim at decreasing the delays in all the steps. With measures and actions derived from implementation science, the median Door to balloon time declined from 94 to 64 minutes between 2005 and 2010 (2).

Nevertheless, Door to balloon time represents only a portion of the total ischemic time and multiple factors need to be addressed to decrease overall ischemic time, specially at centres not capable of primary percutaneous coronary intervention (PCI) facility (3-5).

The importance of swift decision-making in STEMI cases cannot be overstated. However, the delay in making crucial decisions regarding the transfer of STEMI patients to PCI-capable centres remains a persistent challenge in healthcare systems worldwide. One critical metric in this algorithm of management of STEMI cases is the door-in to door-out (DIDO) time, which refers to the duration between a patient's arrival at the hospital and their departure for a primary PCI facility (3,6). This delay is often attributable to several factors, including the complexity of patient presentation, resource availability, and institutional protocols. Nevertheless, one of the most influential factors is the time it takes for physicians to recognize the urgency of the situation and initiate the transfer process. Physician decision time encompasses the period from initial patient evaluation to the decision to transfer for PCI or initiate thrombolytic therapy.

Physicians are the linchpins of STEMI management, responsible for promptly assessing patients and initiating appropriate treatment pathways. However, studies have shown that variations in individual physician practice, clinical judgment, and hesitancy in decision-making significantly contribute to DIDO time delays (7). Despite the existence of evidence-based guidelines and standardized protocols, discrepancies in physician decision time persist, highlighting the urgent need for targeted interventions.

Addressing this primary preventable cause demands a multifaceted approach that encompasses education, protocol adherence, interdisciplinary collaboration, technological innovation, and quality improvement initiatives.

Firstly, continuous medical education programs should prioritize STEMI recognition and management, equipping physicians with the knowledge and confidence to expedite decision-making. Training modules focusing on risk stratification, electrocardiogram interpretation, and the latest treatment algorithms can empower physicians to make timely and informed decisions (8).

Secondly, healthcare institutions must ensure strict adherence to standardized STEMI protocols, with clear pathways for patient evaluation, triage, and transfer (9). Implementing checklist-

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driven approaches and decision support tools can streamline the decision-making process and mitigate diagnostic uncertainty.

Thirdly, fostering a culture of interdisciplinary collaboration is paramount. Effective communication and coordination among emergency physicians, cardiologists, paramedics, and hospital administrators are essential for optimizing STEMI care (10). Regular interdisciplinary meetings and quality improvement initiatives can promote teamwork and accountability across healthcare teams.

Moreover, leveraging technology can expedite STEMI diagnosis and decision-making. Telemedicine platforms and mobile applications for remote consultation and electrocardiogram transmission offer invaluable support, particularly in underserved areas with limited access to specialist care.

Finally, healthcare systems should establish robust performance metrics for STEMI care and implement continuous quality improvement initiatives. By monitoring DIDO time and identifying areas for optimization, healthcare providers can drive ongoing improvements in STEMI management.

In conclusion, addressing the primary preventable cause of DIDO time delay in STEMI—physician decision time—requires a concerted effort from healthcare stakeholders at all levels. By prioritizing education, protocol adherence, collaboration, technological integration, and quality improvement, we can expedite STEMI care, improve patient outcomes, and ultimately save lives.

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EURASIAN JOURNAL OF EMERGENCY MEDICINE
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Acute Kidney Injury in the Emergency Department: Role of Proenkephalin A 119-159

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Abstract

In the emergency department (ED) and critically ill patients in general, acute kidney injury (AKI) is a common complication, and obtaining timely information about kidney function is crucial for initiating protective measures as early as possible. Creatinine-based estimations of the glomerular filtration rate are currently the standard of care, but they are imprecise, prone to errors, and have significant time delays in the identification of reduced kidney function and kidney damage. Emerging research indicates that proenkephalin A 119-159 (penKid) may overcome these drawbacks by indirectly assessing the hormone enkephalin, which stimulates kidney function. This approach offers a more precise evaluation of the kidney. As a novel biomarker for detecting AKI, penKid can be measured immediately upon a patient's arrival at the ED or intensive care unit (ICU), allowing for the early prediction of declining renal function up to 48 h ahead of current diagnostic practices. In summary, penKid offers rapid access to vital information about kidney function for physicians in the ED and ICU. This information complements current diagnostic tools and enables early assessment of renal function. Consequently, penKid can assist clinicians in various clinical scenarios, such as guiding the administration of nephrotoxic drugs or aiding decisions regarding the discontinuation of renal replacement therapy.

Keywords: Acute kidney injury, proenkephalin, emergency department

Introduction

Reduction in kidney function significantly impacts several critically ill patients and is an important contributor to fatal outcomes (1).

More than 13 million cases of acute kidney injury (AKI) are reported annually worldwide, and approximately 30% of patients admitted to an intensive care unit (ICU) develop AKI (2,3). Obtaining timely information about renal function is crucial for initiating nephroprotective strategies early and avoiding nephrotoxic drugs, as these drugs account for approximately one-third of AKI cases in the ICU (4).

This condition refers to an abrupt decrease in kidney function associated with the retention of urea and other nitrogenous waste products and dysregulation of extracellular volume and electrolytes. AKI is currently defined and diagnosed using serum creatinine (sCr) and urine output (5,6), although these data provide limited and delayed information regarding changes in kidney injury and exhibit low sensitivity and specificity (7).

The Kidney Disease: Improving Global Outcomes (KDIGO) definition is the preferred and defines AKI as follows (8):

- Increase in sCr by ≥0.3 mg/dL (≥26.5 micromol/L) within 48 h or,

- Increase in sCr to ≥1.5 time baseline, which is known or presumed to have occurred within the previous 7 days, or,

- Urine volume <0.5 mL/kg/h for 6 h.

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Despite its usefulness for epidemiologic studies, the clinical utility of this definition and staging system remains to be validated. Furthermore, this definition carries several limitations for an emergency physician. Baseline kidney function among patients presenting to the ED is often unknown, and the evaluation of urinary output is not easy to measure with precision in that setting. Finally, such classification does not help in the identification of the etiology of AKI.

The Dark Side of Creatinine

The current standard for renal function evaluation relies on determining an estimated glomerular filtration rate (eGFR) (9). This method suffers from the influence of several factors, such as age, sex, and muscle mass, and is based only on the value of sCr. Several formulas have been developed to account for these confounders, but eGFR may remain imprecise. With the most accurate eGFR equations, the proportion of values that are within 30% of the measured GFR values (P_{30}) generally does not exceed 90%, which is the performance goal for eGFR (6,10,11).

Finally, sCr is unable to detect mild renal failure; its concentration starts to rise above the normal range when almost 50% of the function is already lost. This was described in 1985 as the creatinine-blind area (12).

The Quest for a New Biomarker

In recent years, significant progress has been made in the research of biomarkers aimed at the early identification of AKI (7). Ideally, a good biomarker should be independent of other clinical conditions and possess attributes of easy and precise measurement, and rapid results. It is crucial for this biomarker to exhibit high diagnostic accuracy and be associated with prognostic implications. In addition, there is a need for a reliable biomarker that can help clinicians make informed decisions regarding medical therapy adjustments.

Several candidates are being investigated by different study groups. Among others, some promising biomarkers are proenkephalin A (penKid), cystatin C, neutrophil gelatinase-associated lipocalin, and insulin growth factor binding protein 7 (IGFBP7).

For instance, plasma cystatin C seems to be more sensitive than sCr in detecting reduced kidney function (13,14).

Proenkephalin A 119-159

In healthy states (Figure 1A), kidney function is stimulated by the hormone enkephalin and endogenous opioid peptide. This peptide is derived from the cleavage of proenkephalin A 1-243, but it is unstable and difficult to measure. During this process, another peptide, proenkephalin A 119-159 (penKid), is produced in equimolar concentrations and can be used as a surrogate marker because of its stability (Figure 2).

When kidney function is low (Figure 1B), enkephalin levels rise to stimulate the kidneys. By indirectly measuring enkephalin production, high penKid levels indicate impaired kidney function (15).

Studies have shown that this novel biomarker, penKid, strongly correlates with the measured GFR, the gold standard for the evaluation of kidney function, and its levels are not influenced by age or sex (Figure 3) (16-18).

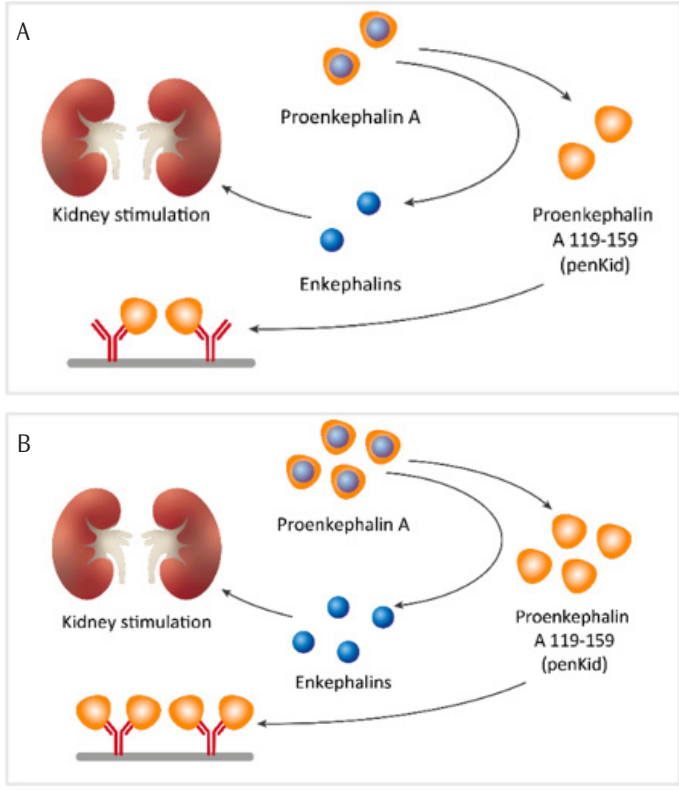

Figure 1. Proenkephalin A production in healthy (A) and ill (B) patients

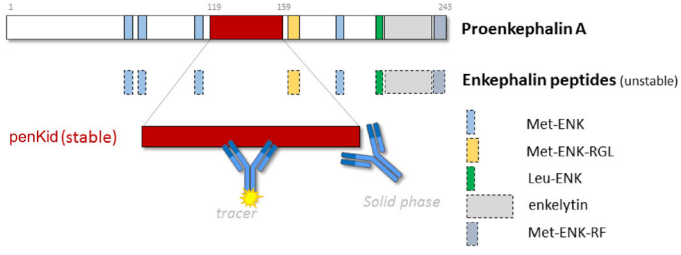

Figure 2. Cleavage of proenkephalin 1-243 results in the release of enkephalin and penKid, among other peptides. PenKid is detected through monoclonal antibodies directed against its middle portion (tracer antibody) and C-terminus (capture antibody on solid phase) (16)

Hollinger et al. (19) showed that penKid predicts future changes in sCr up to two days in advance independently from common comorbidities (e.g. chronic kidney disease, hypertension, and diabetes mellitus), providing physicians with urgently needed information on top of the standard of care. Similar results on the incidence of AKI at 48h and 7 days were reported by Caironi et al. (20) (Figure 4).

PenKid in Critical Care

In emergency settings, it is crucial for the clinician to obtain as much information as possible about patient status. This information will be necessary to make an accurate diagnosis, identify patients at risk of progression, and guide clinical decision-making.

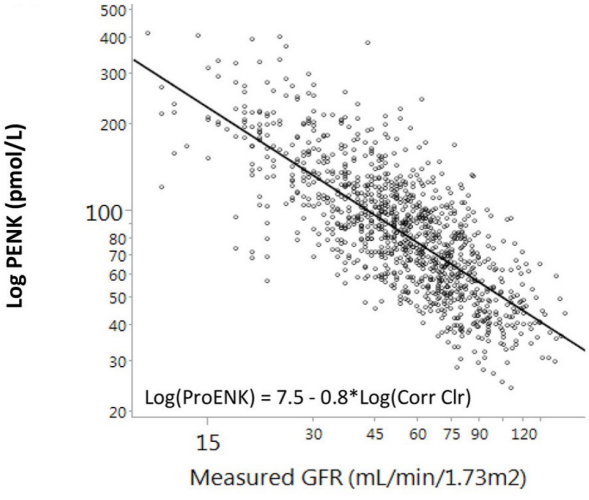

Figure 3. Correlation between penKid and measured GFR (16)
GFR: Glomerular filtration rate

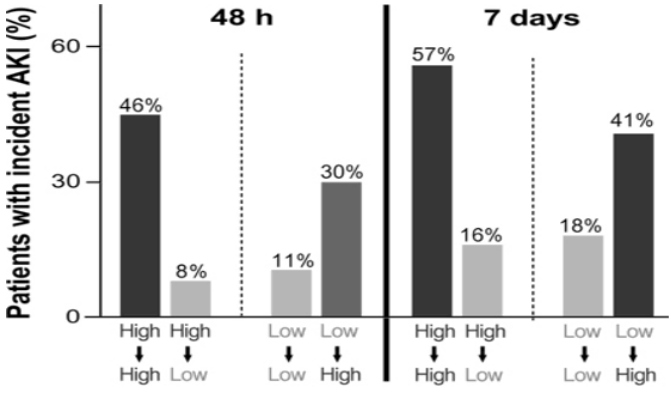

Figure 4. Incidence of AKI at 48 h or 7 h in relation to penKid concentrations on days 1 and 2. Patients were divided into 4 groups, below or above their respective median concentrations on days 1 (78.5 pmol/L) and 2 (70.2 pmol/L) (20)
AKI: Acute kidney injury

Biomarkers, such as high-sensitivity cardiac troponins or procalcitonin (PCT), are well implemented in clinical practice and help clinicians make informed decisions.

PenKid was measured in several cohorts of patients in the ED, and here we provide a summary of the most robust evidence in support of the use of this biomarker for these pathologies.

Acute Heart Failure

Acute heart failure (AHF) is one of the most frequent reasons for presenting to the ED in patients older than 65 years. This condition is defined as a clinical syndrome characterized by a rapid onset of signs and symptoms that reflect an increase in intracardiac pressure or inadequate cardiac output (22). One of the major challenges is identifying patients at risk. To help clinicians correctly stratify the risk of those patients, several scores have been developed, but none of them are still able to predict hospital readmissions with enough precision in the short term (23,24). The guidelines reflect a lack of high-quality data for acute settings (25).

Furthermore, AHF is often complicated by worsening renal function (WRF) and reduced response to diuretic therapy (Figure 5). Therefore, a reliable marker of kidney function would be helpful.

Ng et al. (26) measured penKid in 1,908 patients with AHF, and multivariable Cox regression models showed that penKid level was an independent predictor of 1-year mortality and 1-year death and/or heart failure (HF) [hazard ratio: 1.27; 95% confidence interval (CI): 1.10 to 1.45; p=0.001]. In addition, penKid levels independently predicted outcomes at 3 or 6 months and were independent predictors of in-hospital mortality.

Sepsis and Septic Shock

Sepsis is a leading cause of death worldwide and a major challenge for physicians to predict and manage. The 2021

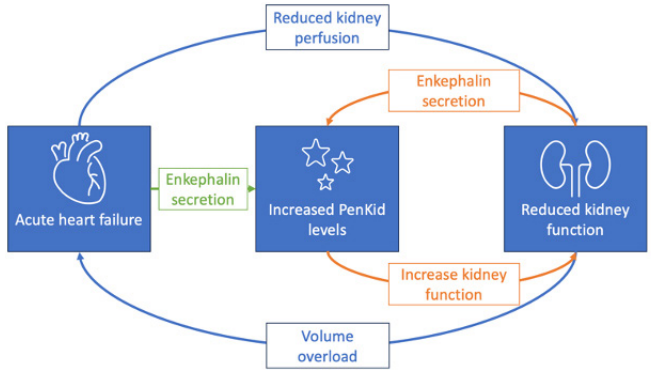

Figure 5. PenKid in acute heart failure (26)

Table 1. Stages of AKI, adapted from the KDIGO Clinical Practice Guidelines for AKI (5)		
Stage	**Serum creatinine**	**Urine output**
1	1.5-1.9 times the baseline *or* ≥0.3 mg/dL (≥26.5 micromol/L) increase	<0.5 mL/kg/h for 6-12 h
2	2.0-2.9 times the baseline	<0.5 mL/kg/h for ≥12 h
3	3 times the baseline *or* ≥4.0 mg/dL (≥353.6 micromol/L) increase or Initiation of RRT *or* Decrease in eGFR <35 mL/min/1.73 m^2 (in patients <18 years)	<0.3 mL/kg/h for ≥24 h *or* Anuria ≥12 h
AKI: Acute kidney injury, KDIGO: Kidney Disease: Improving Global Outcomes, eGFR: Estimated glomerular filtration rate, RRT: Renal replacement therapy		

surviving sepsis campaign guidelines endorse the use of two biomarkers to guide medical therapy (27). Serum lactate levels are recommended to detect peripheral hypoperfusion, and PCT should be used to decide when to stop antimicrobial therapy. These markers alone are not enough.

Recently, new biomarkers have been investigated in this setting, such as bio-adrenomedullin, which can be useful to identify patients at high risk of progression and could be a target for new drugs (28,29).

In septic patients, monitoring renal function is crucial for several reasons. First, kidney function is predictive of mortality and is one of the items in the Sequential Organ Failure Assessment (SOFA) Score, which is used to evaluate the severity of organ failure and predict mortality. Second, antibiotic therapy can be nephrotoxic; therefore, physicians need to tailor it to each patient. Finally, AKI requiring renal replacement therapy (RRT) is one of the most common complications of sepsis and septic shock.

In an analysis involving 956 septic patients, it was observed that penKid exhibited independent predictive abilities for the development of AKI within 48 h and 7 days of hospital admission (20). The adjusted odd ratios were 3.3 (CI: 2.1-5.1) and 2.1 (CI: 1.7-2.8), respectively. Furthermore, the median levels of penKid demonstrated a correlation with the severity of AKI based on the KDIGO stage and renal SOFA score (Figure 6).

High levels of penKid were also associated with all-cause mortality at 28 days in septic patients (Figure 7) (30).

Strong evidence for sepsis also comes from ICU trials, such as the AdrenOSS or the FROG-ICU. In Figure 8 boxplots show the association between the biomarker and different outcomes: major adverse kidney events (MAKEs), AKI, WRF, and need for RRT.

Finally, a recent analysis underlined the predictive role of penKid 30-day mortality in patients with Coronavirus disease-2019

Table 2. Publications on European reference populations		
Population	**Median**	**95th percentile**
Infants (<1 year) (21)	584 (444.4-700.5) pmol/L	
Adults (16)	45 pmol/L	83 pmol/L

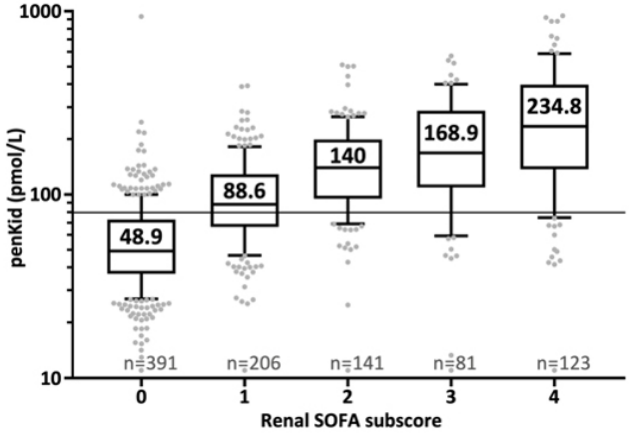

Figure 6. PenKid concentrations at admission in relation to the rSOFA score (20)

rSOFA: Renal Sequential Organ Failure Assessment

(COVID-19) or non-COVID-19 interstitial pneumonia at ED admission (31). The authors did not find a significant difference in penKid concentrations between COVID-positive and COVID-negative patients at admission. A major finding of this study is that higher levels of PenKid at admission correlated with mortality at 30 days, regardless of the etiology of interstitial pneumonia.

Major Burns

Dépret et al. (32) demonstrated, in a cohort of severely ill burned patients (median burn total body surface area was 35%), that

Table 3. Utility of penKid in different conditions and settings	
Disease	**Evidence**
Heart failure	**Acute:** - WRF, in-hospital mortality (33); - 1-year mortality, heart failure rehospitalization, WRF (26); - WRF, 180-day mortality (34).
	Chronic: - MACE (35); - AMI, MACE, hospitalization, 2-years mortality after AMI (36); - In HFpEF patients, rehospitalization at 2 years (37).
Sepsis and septic shock	**ED:** - Progression of renal SOFA, 28-day mortality (30); - 7-day mortality in ED (38).
	ICU: - MAKE, transient AKI, WRF, renal recovery (19); - Need for RRT, improvement in renal function, 90-day mortality (20); - Need for RRT and 30-day mortality (39); - 1-year mortality after ICU discharge (40).
	RRT: - Need for RRT on day one or later during hospitalization (20,41). - Prediction of early and successful liberation from RRT in critically ill patients (42).
Major burns	PenKid highly associated with 90-day mortality and with the development of AKI (32).
Neonates and children	Establishment of penKid reference value in healthy infants; discrimination between AKI and non-AKI children (KDIGO) (21). PenKid levels in neonates and children correlate well with iohexol GFR measurements; discriminates between AKI and non-AKI (43).

WRF: Worsening of renal function, MACE: Major adverse cardiac events, MAKE: Major acute kidney events, HFpEF: Heart failure with preserved ejection fraction, AMI: Acute myocardial infarction, TAAA: Thoraco-abdominal aortic aneurysm, SOFA: Sequential Organ Failure Assessment, RRT: Renal replacement therapy, ICU: Intensive care unit, KDIGO: Kidney Disease: Improving Global Outcomes, ED: Emergency department

Table 4. Selected variables by all-cause mortality within 7 days after admission of patients with sepsis in the ED (38)				
Variable median [interquartile range]	**All (n=101)**	**Dead within 7 days (n=28)**	**7-day survivors (n=73)**	**p value**
PCT (ng/mL)	2.8 [0.6-10.7]	4.1 [1.3-13.0]	2.2 [0.6-9.0]	0.102
penKid (pmol/L)	87 [50-205]	209 [77-499]	75 [47-124]	<0.001
NGAL (µg/mL)	0.6 [0.4-1.2]	1.3 [0.5-2.1]	0.6 [0.3-0.8]	<0.001
Creatinine clearance (mL/min)	48 [23-77]	33 [15-69]	56 [29-81]	0.071
APACHE II score (points)	16 [13-21]	23 [18-27]	14 [12-18]	<0.001

Values are median and interquartile range; p value from non-parametric Kruskal-Wallis test.
PCT: Procalcitonin, NGAL: Neutrophil gelatinase-associated lipocalin, APACHE II: Acute physiology and chronic health evaluation II, ED: Emergency department

high concentrations of penKid at admission correlated with 90-day mortality. Furthermore, this biomarker provided added value to the sCr and SOFA scores in predicting 90-day mortality (combined c-index of 0.738 versus 0.707; p=0.024 and 0.787 versus 0.752; p<0.001).

Implementation in the Emergency Department

Given the evidence, several reasons support the use of penKid in the ED. First, for the early detection of AKI and therefore to allow healthcare providers to initiate prompt treatment and prevent further damage to the kidneys. Second, the role in risk stratification. In fact, penKid levels can help assess the severity and prognosis of AKI. Higher penKid levels often indicate more severe kidney injury and may be associated with a worse clinical outcome. By measuring penKid, healthcare providers can identify patients at a higher risk of complications and provide appropriate management strategies. Finally, to monitor the treatment response in patients with AKI.

These recommendations apply to all patients who may develop AKI, but especially in those with sepsis, AHF, and major burns for which the evidence is stronger and there is a clear risk of worsening kidney function.

Marino et al. (38) described how, in patients with sepsis in the ED, penKid was significantly higher in those who died within 7 days from presentation (Table 4). In contrast, there was no difference in the values of PCT and creatinine clearance between the groups,

	All patients	Quartile I	Quartile II	Quartile III	Quartile IV
penKid (pmol/L)	77.9 (10.9-843.0)	10.9-56.9	57.0-77.9	78.1-119.4	120.0-843.0

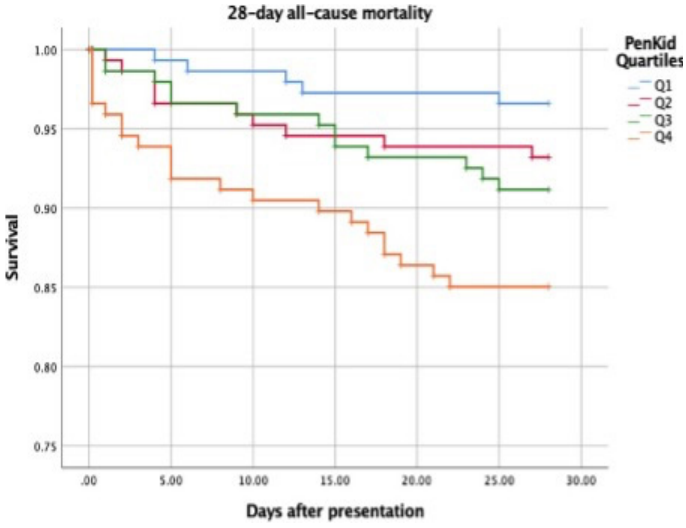

Figure 7. Unadjusted Kaplan-Meier plot showing 28-day all-cause mortality for penKid quartiles (30)

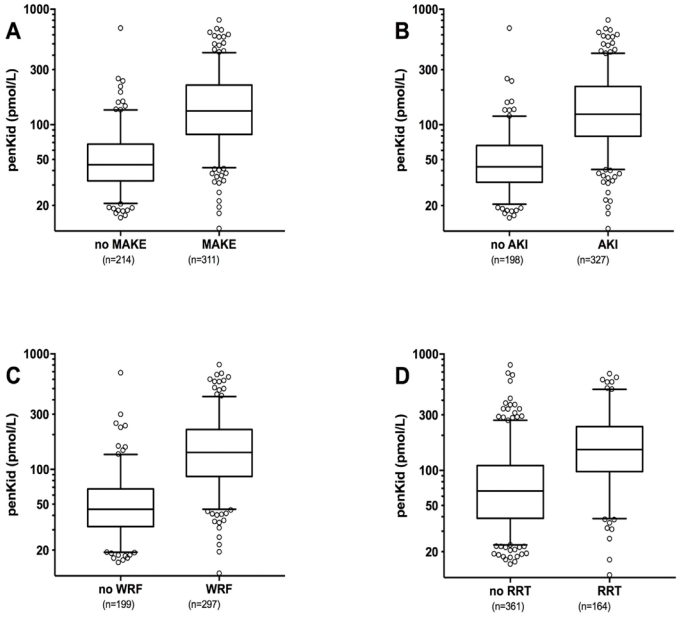

Figure 8. PenKid values at admission were compared in the FROG-ICU cohort across various groups: (A) patients with or without MAKEs at day 7, (B) patients with AKI compared with those without, (C) patients with WRF compared with those without, and (D) patients with or without RRT (19)

AKI: Acute kidney injury, ICU: Intensive care unit, MAKEs: Major adverse kidney events, WRF: Worsening of renal function, RRT: Renal replacement therapy

confirming that penKid could help clinicians identify high-risk patients, in addition to the already established biomarkers.

We suggest that patients with elevated penKid values should be carefully evaluated by a clinician to identify the possible cause of AKI. According to the findings, treatment strategies may include fluid resuscitation, medication adjustments, discontinuation of nephrotoxic drugs, and interventions to improve kidney perfusion. It is also important to closely monitor the patient, provide appropriate supportive care, and potentially consult a nephrologist for further management. Selected cases, such as severe AKI with high penKid levels, may require more aggressive interventions, such as RRT, to support kidney function and prevent complications such as electrolyte imbalances and fluid overload.

Although larger studies would be necessary to establish a standardized cut-off, Donato et al. (16) calculated the 95th percentile in a cohort of 100 adult healthy donors without (bleeding/clotting, diabetes, HF or other cardiovascular events, kidney disease, cancer, cardiovascular disorders) after a minimum 12-h fast. They derived a value of 83 pmol/L (70-92 pmol/L), with a median of 48.1 pmol/L (41.7-55.7 pmol/L), in that population.

In support of this finding, Hollinger et al. (19) reported that patients with a value above 84 pmol/L, the median value in their population, had a higher rate of MAKE and WRF and were at a higher risk of 28-day mortality compared with patients with a value below 84 pmol/L.

Other Settings

Scientific experts agree on the significant need for new biomarkers that timely mirror kidney function, thereby improving the prediction and monitoring of AKI, MAKE, and RRT (7). In addition, many other concrete clinical cases may also benefit from these developments, for instance, guidance on starting or stopping RRT, guidance on nephrotoxic drug administration, hospitalization decisions after catheterization-laboratory procedures, prediction of delayed graft function, and assessment of contrast-induced nephropathy.

Another setting that has been described in the literature is patients with chronic HF (CHF). Matsue et al. (34) measured penKid in a cohort of 95 patients with CHF together with other measures of kidney function, such as renal blood flow (RBF) and GFR, using ^{131}I-Hippuran and ^{125}I-iothalamate clearances, respectively. In these patients, penKid was strongly correlated with both RBF ($p<0.001$) and GFR ($p<0.001$), but not with renal tubular markers. Furthermore, in patients with acutely decompensated chronic HF and preserved ejection fraction, multivariate Cox regression models showed that penKid predicted the composite endpoint

of 2-year death/HF [HR 1.45 (95% CI: 1.12-1.88, p=0.005)], even after adjustment for troponin [HR 1.59 (1.14-2.20, p=0.006)], and body mass index [HR 1.63 (1.13-2.33, p=0.009)] (37).

Conclusion

AKI poses several challenges for physicians in clinical practice, from early identification to monitoring during treatment. In this setting, penKid can offer access to vital information about kidney function, providing added value to the existing standard of care, especially in the ED and ICU. This information complements current diagnostic tools and enables early assessment of renal function. Therefore, this novel biomarker can assist clinicians in various clinical scenarios, such as guiding the administration of nephrotoxic drugs or making decisions regarding the discontinuation of RRT.

Ethics

Authorship Contributions

Concept: L.C., Analysis or Interpretation: L.C., S.D.S., Literature Search: L.C., S.D.S., Writing: L.C., S.D.S.

Conflict of Interest: No conflict of interest was declared by the authors.

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Primary Preventable Cause of Door-in to Door-out Time Delay in ST-elavation Miyocard Infarction: Physician Decision Time

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Abstract

Aim: Door-in to door-out (DIDO) time is defined as the process of primary percutaneous coronary intervention after the first medical contact. In patients with ST-segment elevation myocardial infarction, this period commonly causes delays in the patient's treatment. Our aim is to determine the preventable component among the components that make up the DIDO time.

Materials and Methods: The study included 86 patients with ST-segment elevation myocardial infarction who were referred from non-percutaneous coronary intervention-capable hospitals to our percutaneous coronary intervention center. In this study, the DIDO time for transferred patients was divided into three determining components: the door-to-electrocardiography time, physician decision time (PDT), and time to referral.

Results: The DIDO time was >30 min in 91.9% of 86 patients referred for primary percutaneous coronary intervention from non- percutaneous coronary intervention-capable hospitals. The mean DIDO time was 85 (3-233) minutes. The main component prolonging the DIDO time in all groups was the "PDT", defined for the first time in this study, with a median of 49 (1-186) minutes.

Conclusion: Thanks to the data we have uncovered, a time recommendation should be developed for each stage of the transfer comprising the DIDO components. Developing standard recommendations can help define and reinforce time standards to ultimately reduce DIDO times and improve patient care.

Keywords: Acute myocardial infarction, door-in to door-out, emergency department, primary percutaneous coronary intervention, interhospital transfer

Introduction

In patients with acute ST-segment elevation myocardial infarction (STEMI), prolonged time from symptom onset to wire crossing of the responsible artery has been associated with mortality. Myocardial ischemia time is an important determinant of infarct size in patients with STEMI. Rapid identification and early treatment of acute STEMI are critical for reducing morbidity and mortality (1,2).

Guidelines recommend diagnosis within 10 min of first medical contact (FMC) in patients with suspected STEMI and initiation of primary percutaneous coronary intervention (PPCI) by transferring the patient to the PPCI center within 120 min. The recommended door-to-balloon time (D2B) of a maximum of 120 min and the door-in to door-out (DIDO) time of 30 min (time to discharge from the referral hospital for transfer to a PCI center) are often prolonged due to multiple factors (3-8).

Delays from symptom onset to the PPCI procedure are caused by two main factors: patient and system. Patient-related delay defines the time from the onset of symptoms to FMC, and system-related delay defines the time from diagnosis to treatment with reperfusion therapy (9). DIDO time is one of the critical steps of system-related delays; however, data on the components affecting this time are limited. This study aimed to reveal the median time of the components affecting DIDO time in patients referred to the PCI center after FMC.

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Materials and Methods

Study Design: This was a prospective observational study conducted at the Department of Emergency Medicine, Zonguldak Bülent Ecevit University Faculty of Medicine.

Patients: This study included STEMI patients who were referred from non-PCI-capable hospitals to our PCI center hospital between 01.09.2019 and 31.10.2019. Patients whose duration could not be determined because of incomplete files were excluded from the study. The distances from non-PCI-capable hospitals to our hospital ranged between 6.8 and 39.8 miles, and the Google Maps estimated driving times were 19-62 minutes.

Study Protocol*:* Demographic data of all patients, referral center information, the times of referral stages that may have caused a system-related delay, whether troponin results were awaited, time of admission to the PCI center, and time of initiation of PPCI were recorded on the case forms.

FMC PPCI initiation times were divided into three categories as <90 minutes, 90-120 minutes, and >120 min.

DIDO time**;** was considered the duration from arrival to discharge at the first hospital to transfer from that hospital to the percutaneous coronary intervention hospital.

The components determining the duration of DIDO time after the FMC were classified into three categories (Figure 1).

1. Door-to-electrocardiography (ECG) time: The time from hospital admission to ECG.

2. Physician decision time (PDT): The time elapsed from the time written in the referral request form until ECG is performed (physician is the emergency department physician who meets the patient in the emergency department).

3. Time taken to start the referral: Time elapsed from the time written in the referral request form to the ambulance receiving the case.

The centers where STEMI patients first applied were divided into 3 categories.

1. City Center Level 2 Hospital: Urban Level 2 Non-PCI-capable hospitals close to the PCI center,

2. Town Level 2 Hospital: Level 2 Non-PCI-capable hospitals in towns far from the PCI center,

3. City Center Level 1 Outpatient Clinic: Neighborhood polyclinics close to the PCI center.

The FMC times of the patients were divided into three groups according to the time of admission: day, evening, and night. Patient applications between 08:00 and 17:00 were categorized as daytime, between 17:01 and 24:00 as in the evening, and between 00:01 and 07:59 as at night.

The FMC times of the patients were divided into two groups according to the days of admission: weekdays and weekends.

Ethical Approval: The research was submitted to the Clinical Research Ethics Committee at Zonguldak Bülent Ecevit University and approved under certificate number 2019-128-21/08, date: 21.08.2019.

Statistical Analysis

Descriptive statistics for categorical variables are given in percentages. Continuous variables were compared using

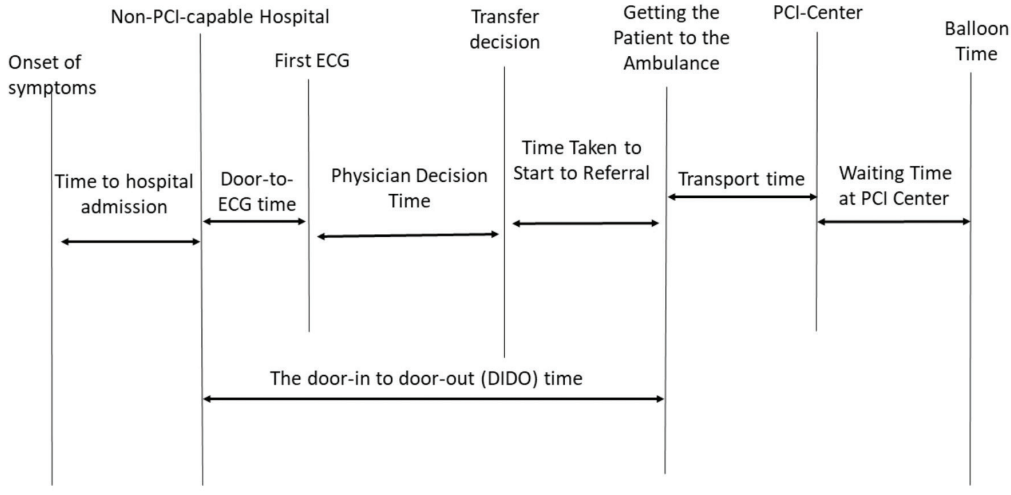

Figure 1. Components of the time from onset of STEMI patient's symptoms to initiation of the PCI procedure

PCI: Percutaneous coronary intervention, ECG: Electrocardiography, STEMI: ST-segment elevation myocardial infarction

Student's t-test or Wilcoxon test between two groups and with one-way analysis of variance between three or more groups. Categorical variables were compared using the chi-square independence test. All tests were two-tailed; $p<0.05$ was considered statistically significant. Statistical analyses were performed using Statistical Package for the Social Sciences 25.0.

Results

A total of 86 patients, 63 males and 23 females, were included in the study. The mean age was 59.05 years [stardard deviation (SD): 10.87 for men and 70.65 years (SD: 12.86) for women.

Of the 86 patients, 35 (40.7%) were admitted to a city center level 2 hospital, 46 (53%) were admitted to a Town Level 2 hospital, and 5 (5.8%) were admitted to a level 1 outpatient clinic. Of these patients, 71 (82.6%) were admitted to the emergency department by their own means, and 15 (17.4%) were admitted to the emergency department by ambulance.

Sixty-four (74.4%) patients visited the emergency department on weekdays and 22 (25.6%) on weekends.

Of the patients, 43 (50.0%) applied between 08:00 and 17:00, 31 (36.0%) between 17:01 and 24:00, and 12 (14.0%) between 24:01 and 07:59.

After the FMC, PPCI was performed within >120 min in 51 (59.3%) patients, within 90-120 min in 23 (26.7%), and within <90 minutes in 12 (14.0%) patients.

The median D2B was 166 (122-365) minutes in the group with D2B >120 minutes, 109 (91-120) minutes in the group with 90 <D2B <120 minutes, and 77 (50-90) minutes in the group with D2B <90 minutes.

The median D2B was 110 (50-365) minutes in the FMC City Center Level 2 group, 159.5 (63-343) minutes in the Town Level 2 group, and 126 (65-250) minutes in the City Center Level 1 Outpatient Clinic group.

DIDO time was >30 min in 79 (91.9%) of 86 patients referred for PPCI from non-PCI-capable hospitals. The mean DIDO time was 74.5 (3-233) minutes.

Median DIDO times were 98 (39-233) minutes in the group with a D2B >120 min, 55 (16-85) minutes in the 90-120 min group, and 42 (3-55) minutes in the <90-minute group.

Median DIDO times were 65 (15-199) minutes in the FMC City Center Level 2 group, 79.5 (3-233) minutes in the Town Level 2 group, and 70 (21-177) minutes in the City Center Level 1 Outpatient Clinic group.

In all patient groups, the main component causing prolongation of D2B was a delay in DIDO time with a median of 74.5 (3-233) minutes. The main component prolonging the DIDO time in all groups was PDT with a median of 49 (1-186) minutes. In groups with FMC-PPCI duration <90 minutes, 90-120 minutes, and >120 min, PDT was 12, 37, and 62 min, respectively. By hospital category, that is, in city center level 2, Town Level 2, and city center level 1 non-capable PCI hospitals, PDT was 40, 53, and 43 min, respectively.

Table 1 shows the relationship between the D2B and the time spent on the components that cause the prolongation of DIDO.

D2B time >120 min was more common in the group with FMC on weekdays than in the group with FMC on weekends (64.1% vs. 45.5%). In the group with FMC time between 24.01 and 07.59, D2B time >120 min was more common than in the 17:01-24:00 and 08:00-17:00 groups (83.3% vs. 61.3-51.2%) (Table 2).

Table 1. Relationship between the D2B time and the time spent on the components causing the prolongation of DIDO

		DIDO time			DIDO time (min)
		Door-to-ECG time (min)	PDT (min)	Time taken to start to referral (min)	
D2B time (min)					
<90 min	Mean	7.83	18.33	9.00	35.17
	SD	7.23	15.18	5.97	17.97
	Minimum	1	1	1	3
	Maximum	24	40	18	55
	Median	**5**	**12**	**7.5**	**42**
90-120 min	Mean	10.00	33.74	14.00	57.74
	SD	10.71	19.17	9.88	18.21
	Minimum	1	3	1	16
	Maximum	51	67	45	85
	Median	**6**	**37**	**10**	**55**

Table 1. Continued

		DIDO time			DIDO time (min)
		Door-to-ECG time (min)	PDT (min)	Time taken to start to referral (min)	
D2B time (min)					
>120 min	Mean	21.41	73.20	14.65	109.26
	SD	29.03	40.94	11.86	50.05
	Minimum	1	10	1	39
	Maximum	170	186	58	233
	Median	**13**	**62**	**10**	**98**
In all patients	Mean	16.47	54.99	13.69	85.14
	SD	23.75	40.27	10.78	50.06
	Minimum	1	1	1	3
	Maximum	170	186	58	233
	Median	**10**	**49**	**10**	**74.5**
p value*		**0.031**	**0.000**	**0.263**	**0.000**
First applied hospital					
City Center Level 2 Hospital	Mean	12.31	43.11	15.34	70.77
	SD	12.02	31.46	12.61	36.77
	Minimum	1	3	1	15
	Maximum	51	144	58	199
	Median	**8**	**40**	**12**	**65**
Town Level 2 Hospital	Mean	19.70	64.37	12.41	96.47
	SD	30.37	44.23	9.14	55.58
	Minimum	1	1	1	3
	Maximum	170	186	45	233
	Median	**11.50**	**53**	**10**	**79.50**
City Center Level 1 Outpatient Clinic	Mean	15.80	51.80	13.80	81.40
	SD	14.45	42.19	11.65	60.88
	Minimum	2	6	1	21
	Maximum	35	120	30	177
	Median	**10**	**43**	**13**	**70**
In all patients	Mean	16.47	54.99	13.69	85.13
	SD	23.85	40.27	10.78	50.06
	Minimum	1	1	1	3
	Maximum	170	186	58	233
	Median	**10**	**49**	**10**	**74.5**
p value*		**0.309**	**0.040**	**0.549**	**0.042**

*ANOVA test.
D2B: Door to balloon time, DIDO: Door-in to door-out, PDT: Physician decision time, ECG: Electrocardiogram, PCI: Percutaneous coronary intervention, FMC: First medical contact, PPCI: Primary percutaneous coronary intervention, min: Minute, SD: Standard deviation

Table 2. Relationship between D2B times by day and time of first medical contact

		D2B time			p value*
		<90 min n (%)	90-120 min n (%)	>120 min n (%)	
First medical contact days	Weekdays	10 (15.6)	13 (20.3)	41 (64.1)	0.07
	Weekends	2 (9.1)	10 (45.5)	10 (45.5)	
First medical contact hours	08:00-17:00	6 (14.0)	15 (34.9)	22 (51.2)	0.188
	17:01-24:00	6 (19.4)	6 (19.4)	19 (61.3)	
	24:01-07:59	0 (0.0)	2 (16.7)	10 (83.3)	

*Chi-square, Fisher's exact test.
D2B: Door to balloon time, min: Minute

The median DIDO time was 75 (3-203) and 57.5 (28-233) minutes in the groups with FMC on weekdays and weekends, respectively. In both groups, the main component prolonging DIDO time was PDT with 52 (1-186) and 40 (5-75) minutes, respectively.

In the groups with FMC times of 08:00-17:00, 17:01-24:00, and 24:01-07:59, the median DIDO time was 75 (3-199), 60 (16-233), and 89 (53-233) min, respectively. In all three groups, the main component prolonging DIDO time was PDT with 49 (1-144), 35 (6-175), and 72 (37-186) min, respectively. The longest PDT time occurred in patients admitted between 24:01-07:59 h, with 72 min.

Table 3 shows the relationship between whether the FMC is on a weekday or on a weekend, while of day the application is made, and the processes until the start of the procedure.

Troponin level was awaited to make a diagnosis in 57.8% of STEMI patients admitted to the Town Level 2 hospital and in 37.1% of the patients admitted to the City Center Level 2 hospital. On the other hand, 66.7% of the patients with D2B time >120 min waited for the troponin result to be diagnosed (Table 4).

Table 3. Relationship between first medical contact days and hours with time spent in DIDO components

		DIDO time			DIDO time (min)
		Door-to-ECG time (min)	PDT (min)	Time taken to start the referral	
First medical contact days					
Weekdays	Mean	15.33	57.52	13.23	86.08
	SD	18.51	40.82	11.17	47.77
	Minimum	1	1	1	3
	Maximum	124	186	58	203
	Median	**10**	**52**	**10**	**75**
Weekends	Mean	19.77	47.64	15	82.41
	SD	35.48	38.56	9.70	57.32
	Minimum	1	5	4	28
	Maximum	170	175	45	233
	Median	**9.5**	**40**	**13**	**57.5**
p value*		**0.485**	**0.280**	**0.558**	**0.687**
First medical contact hours					
08:00-17:00	Mean	13.3	52.26	14.14	79.70
	SD	12.1	36.34	11.47	42.89
	Minimum	1	1	1	3
	Maximum	51	144	45	199
	Median	**10**	**49**	**10**	**75**
17:01-24:00	Mean	21.94	45.71	13.10	80.74
	SD	35.97	37.96	10.66	54.86
	Minimum	1	6	1	16
	Maximum	170	175	58	233
	Median	**10**	**35**	**10**	**60**
24:01-07:59	Mean	13.67	88.75	13.58	116
	SD	13.26	45.20	9.17	54.06
	Minimum	1	37	2	53
	Maximum	45	186	32	233
	Median	**10**	**72**	**11**	**89.0**
p value**		**0.259**	**0.005**	**0.867**	**0.077**

*Independent sample t-test.
**ANOVA.
DIDO: Door-in to door-out, min: Minute, SD: Standard deviation

Table 4. The centers where the patients applied, the time taken to perform PPCI, and the number of patients whose troponin result is awaited for diagnosis

	Troponin result		p value*
	Awaited n (%)	No awaited n (%)	
First applied hospital			
City Center Level 2 Hospital	22 (62.9)	13 (37.1)	
Town Level 2 Hospital	19 (41.3)	27 (58.7)	
City Center Level 1 Outpatient Clinic	3 (60)	2 (40)	
In all patients	44 (51.2)	42 (48.8)	
FMC-PPCI time (min)			
<90 min	11 (91.7)	1 (8.3)	0.148
90-120 min	16 (69.6)	7 (30.4)	
>120 min	17 (33.3)	34 (66.7)	
In all patients	44 (51.2)	42 (48.8)	

*Chi-square, Fisher's exact test.
PCI: Percutaneous coronary intervention, FMC: First medical contact, PPCI: Primary percutaneous coronary intervention, min: Minute

Discussion

All over the world, FMC of STEMI patients frequently occurs in non-PCI-capable hospitals, necessitating their transfer to a PCI-capable hospital (10-13). For STEMI patients requiring interhospital transfer for PPCI, the recommended D2B time is a maximum of 120 min. However, in most patients, this transfer occurs over the recommended times. The most important component of these system-related delays is the DIDO time (6).

However, only 8.1% of our patients could meet a DIDO time of 30 min as recommended in the guidelines. In the literature, the rates of compliance with the DIDO time are between 20.1% and 2.1% (3,14-16).

Despite many studies on variables that may affect the DIDO time, such as whether ECG is taken before the hospital, the patient's age, ethnicity, comorbidities, the vehicle chosen for transfer, longer symptom duration, and distance between centers, there is not enough data on the components that make up the DIDO time (3,11,14,17). In addition, no suggestions have been made regarding the duration of the components that make up the DIDO time. Identifying the components that constitute the DIDO time and providing reasonable suggestions during these components may help shorten this period.

Our study revealed that the most important preventable parameter in prolonging the DIDO time was PDT, which was defined for the first time in this study, and its median value was 49 (1-186) minutes. This finding adds new data consistent with the existing literature on referral hospital-related DIDO time delay (2,14).

Delays in the referral decision of physicians may be caused by delays in evaluating the ECG taken by the nurse, being unsure of the diagnosis of STEMI, not being able to convince the PCI center physician without a troponin result, the need for cardiologist approval for the referral decision, overcrowding in the emergency room, etc. Additional detailed studies are needed to uncover the causes of PDT prolongation, which is one of the most important components of DIDO time in STEMI patients.

Other data revealed in this study is that DIDO time was longer during weekdays and working hours. However, existing literature suggests that this period is longer, especially for those who apply on weekends and outside working hours (5). We think this may be due to various reasons, such as the intervention of the procedures in the decision-making mechanisms on weekdays and during working hours, the concern to follow the specialist's tendency, and the PCI center serving patients with other appointments. However, more detailed studies are required to clarify this issue.

Developing standard time recommendations for each procedure from the moment a patient with suspected STEMI presents to a non-PCI-capable hospital until the patient reaches the catheterization laboratory may prompt hospitals and teams to act more carefully.

Study Limitations

Because this study considered the documented times, it was not possible to deduce whether these periods were extended due to procedural reasons. Even so, since these are the written documents that will initiate the process, recorded deadlines were accepted as realistic timings.

This small, single-center, observational study only provides limited generalizability; therefore, multicenter studies are needed.

Conclusion

Our study found that the most important preventable step of delayed DIDO time was PDT, with a median of 49 (1-186) minutes. We believe that a time recommendation should be developed for each stage of the transfer, making up the DIDO components. Developing standard recommendations can help define and reinforce time standards to ultimately reduce DIDO times and improve patient care.

Ethics

Ethics Committee Approval: The research was submitted to the Clinical Research Ethics Committee at Zonguldak Bülent Ecevit University and approved under certificate number: 2019-128-21/08, date: 21.08.2019.

Informed Consent: Consent form was filled out by all participants.

Authorship Contributions

Surgical and Medical Practices - Concept - Design - Data Collection or Processing - Analysis or Interpretation - Literature Search - Writing: H.H., A.C.H.

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Factors Affecting the Self-efficacy, Self Competency, and Willingness of Medical Students in Disasters

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Abstract

Aim: During times of disasters, healthcare professionals often face pressure and need additional support in care areas. This study assesses the potential role of medical students in disaster response and the influencing factors, including their involvement in the TEAMS project.

Materials and Methods: An observational survey-based study was conducted at a university to assess the motivation and competency of undergraduate students toward disaster response. To collect data, the questionnaire was distributed using Google Forms. The homogeneity of items in the subscales of the questionnaire was evaluated using Cronbach's alpha, and the questionnaire results were compared with the categorical variables using the t-test.

Results: TEAMS participants demonstrated a higher level of competence in trauma care and drug/injection administration ($p<0.05$). Individuals who received disaster training exhibited increased competency in triage, trauma care, drug/injection administration, patient follow-up, and psychological support ($p<0.05$). Sixth-year students feel more proficient in trauma care, psychological support, community health services, and public relation work.

Conclusion: Students are willing to contribute to disaster relief efforts, but their motivation is enhanced when they feel psychologically and medically prepared. Active involvement in disaster training programs plays a significant role in increasing students' competence.

Keywords: Disaster medicine, disaster preparedness, volunteering, disaster management

Introduction

Healthcare workers play a crucial role in disaster management, and their decisions can have a significant impact during emergencies. However, in countries where disaster management education is inadequate, medical professionals may lack the necessary expertize knowledge, and preparedness to manage disasters effectively, potentially leading to further escalation (1). During disasters, qualified healthcare workers, including doctors, registered nurses, health technicians, and emergency medical technicians, may be under immense pressure, necessitating assistance in areas beyond direct patient care. Hence, the demand for volunteer workers during disasters is becoming increasingly pertinent and debated. The potential contribution of medical school students to disaster response has been discussed in the literature, especially during events such as the Coronavirus disease-2019 pandemic (2). In countries such as Turkey, where hospitals are frequently overcrowded (3), medical students can provide valuable support, particularly since medical faculties are usually located close to hospitals (4,5). These students can respond rapidly to emergency calls, given the flexible nature of their daily responsibilities. With adequate training, they can perform specific roles as part of a team (6). However, minimal education is provided in medical schools on disaster management, and students may lack the general knowledge required to competently manage such roles. Therefore, infrastructure development and provision

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of education and training are necessary to ensure that students are adequately prepared to perform these roles safely (7).

The TEAMS project, funded by the European Union Humanitarian Aid and Civil Protection, aims to develop a standardized, cost-effective training package focused on operational team training for emergency response teams, pilot implementation, and evaluation. In a pilot study conducted in Turkey between August 2 and 7, 2022, medical students participated as role players, facilitators, interpreters, and observers in functional and tabletop exercises simulating disasters.

In this study, we aimed to evaluate the willingness of medical students to respond to disasters, the roles they prefer to be assigned to, and the factors that influence their decision-making, including their participation in the TEAMS project.

Materials and Methods

A cross-sectional quantitative observational survey-based study was conducted to assess the motivation and attitude of undergraduate students in their fifth or sixth semester regarding disaster response at a İstanbul Medeniyet University. The Institutional Review Board of the İstanbul Medeniyet University approved the study, and the medical college's administrative division also consented to the participation of medical students. The participants were contacted via phone, WhatsApp, and personal mail addresses and were provided with a consent form to acknowledge their willingness to participate in the study. All undergraduate students in the fifth and sixth semesters İstanbul Medeniyet University's Faculty of Medicine were included in the study without any exclusion criteria.

Study Questionnaire

For our research, the survey questions were developed on the basis of a review of relevant literature (8-13). The survey questions presented here have been rated using a Likert scale, where zero denotes strong disagreement and five denotes strong agreement. In this study, fifteen questions were prepared for students to self-assess their readiness to participate in disaster relief efforts, while 25 questions evaluated the factors that influence their volunteering decisions across different disaster scenarios. Furthermore, the study investigated the students' preferences regarding the specific hospital departments where they would like to volunteer during a disaster, as well as the areas where they perceive themselves to be competent. The relationships between volunteering behavior, self-perceived competency, and demographic variables such as semester, age, gender, dependent status, and prior participation in disaster education were also examined. The questionnaire was disseminated using Google Forms.

The question, "What are the potential barriers to volunteerism in disaster response from your perspective?" was designed to elicit open-ended responses to determine obstacles that could discourage students from volunteering during crises. Answers to this open-ended inquiry were meticulously coded and input into an anonymous database for examination using Stata 11, a software product from Stata Corp. College Station, TX, USA.

The collected narratives were subjected to independent review and compilation via a qualitative thematic framework undertaken by the research team members. As emerging results were identified, they were deliberated upon, and themes were negotiated and agreed to. The research team, which was composed of emergency medicine professionals, validated the interpretations.

Roles of Students in the TEAMS 3.0 Project

As part of Turkey's contribution to the TEAMS 3.0 project, students assumed various roles in different emergency response scenarios. For instance, in the mass casualty response scenario, students functioned as patients and visited a field hospital following an aftershock. In the biological agent response scenario, they played the roles of both a sample patient and a patient's family member. Furthermore, in planning the exit scenario, they assumed the role of a journalist (14).

During the project's training of the trainee segment, students participated in courses on the importance of team roles in disasters, field hospital setup, mass casualty management, triage, and ethical issues in disasters. In addition, as part of this international project, students also took on administrative tasks, such as English-Turkish translation and assisting trainers.

The research was submitted to the Clinical Research Ethics Committee at University of Health Sciences Turkey, İstanbul Medeniyet University, Göztepe Training and Research Hospital and approved under decision number: 2022/0760, date: 21.12.2022.

Statistical Analysis

The data obtained from the surveys that were distributed using Google Forms were analyzed using the Statistical Package for Social Sciences (SPSS) (SPSS 26; IBM Inc., Chicago, IL, USA). The categorical variables were expressed as frequencies and percentages, and the chi-square test was used to analyze them. The homogeneity of items in the subscales of the questionnaire was evaluated using Cronbach's alpha, and the questionnaire results were compared with the categorical variables using the t-test. A p value of 0.05 was considered statistically significant.

Results

In this study, 172 participants, consisting of 71 (41.3%) males and 101 (58.7%) females, participated. The mean age of the participants was found to be 23.59±2.088. Of the total participants, 55 (32.0%) were from the fifth semester, while 117 (68.0%) were from the sixth semester. Additionally, 17 participants (9.9%) reported attending disaster courses, whereas 38 participants (22.1%) reported participating in the TEAMS project. Furthermore, 59 participants (34.8%) reported receiving disaster education during their medical studies.

Moreover, 55 participants (32%) reported having a dependent individual in their family. Thirty students participated in the TEAMS project as role models, focusing on topics such as mass casualties and Severe acute respiratory syndrome, while eight students served in administrative roles such as facilitators and translators, aiding the trainers.

Tables 1-3 provide an overview of the factors that affect students' self-assessment, motivation, and willingness and selection of hospital areas to intervene in natural disasters, mass casualty incidents, and pandemic outbreaks.

Self-reported competency and their preferred work areas, as well as the factors that influence self-supported competency.

Participants in the TEAMS training felt more competent in trauma care and drug/injection administration ($p<0.05$) compared to those who were not. Those who received disaster training felt more competent in triage, trauma care, drug/injection administration, patient follow-up, and psychological support ($p<0.05$). Males felt more competent in critical care ($p<0.05$), whereas sixth-semester students felt more competent in trauma care, psychological support, community health services, and public relations work.

Table 1. Factors effecting self-competency of medical students in disaster response

	Sex	Semester	Disaster education	TEAMS' project participation	Dependent person in household	Mean±SD	Cronbach
I can identify the relative damage caused by the disaster	**0.04**	0.547	**0.000**	**0.001**	0.059	3.01±0.98	0.896
I can assess wounds accurately and quickly	**0.031**	0.115	**0.001**	**0.010**	0.149	3.21±0.91	0.895
I can assess epidemic situations such as infectious diseases or acute poisoning that may occur after a disaster	0.121	0.064	**0.001**	**0.000**	0.056	2.82±0.98	0.897
I can recognize vulnerable groups such as chronically ill and disabled people	0.442	0.964	**0.013**	**0.048**	0.090	3.82±0.83	0.902
I can perform triage	0.155	0.109	**0.003**	**0.007**	0.218	3.64±0.92	0.899
I can perform debridement, hemostasis, bandaging and splinting/limb fixation	0.134	0.096	**0.050**	**0.044**	**0.035**	3.31±1.10	0.899
I can lift the wounded at the moment of transfer	**0.000**	0.347	0.213	0.169	**0.018**	2.90±1.22	0.901
I can transport the wounded	**0.002**	0.928	0.058	0.085	**0.003**	2.98±1.07	0.895
I can apply emergency rescue techniques	**0.004**	0.241	**0.002**	0.034	**0.003**	3.20±1.03	0.897
I can do intensive care and patient care of critically ill patients	0.121	0.585	**0.003**	0.054	0.053	2.46±0.97	0.898
I can prevent and control infectious diseases in the disaster area	0.984	0.050	**0.000**	0.000	**0.046**	2.80±1.04	0.900
I can quickly adapt to the work environment by adjusting my own psychological state	**0.001**	0.993	**0.011**	0.101	**0.006**	3.44±1.10	0.904
I can communicate with other team members to create a good collaborative relationship	0.173	0.633	0.171	0.734	**0.010**	4.07±0.85	0.904
I can communicate effectively with disaster survivors and their relatives and create a good provider-patient relationship	0.990	0.610	0.480	0.835	0.228	3.76±0.92	0.901
I can comply with professional ethical rules with a humane approach, empathy and love	0.548	0.675	0.529	0.857	0.116	4.22±0.84	0.907
P1 total							0.0906

SD: Standard deviation

Students who feel competent in triage, patient follow-up, and community health prefer to work in triage; those who feel competent in trauma care and drug/injection administration prefer to work in the emergency room; and those who feel competent in trauma care prefer to work in the ambulance ($p<0.05$). Those who felt competent in triage, trauma care, critical care, drug/injection administration, patient follow-up, and porter work preferred to work in the trauma area ($p<0.05$), whereas those who felt competent in-patient follow-up and critical care preferred to work in the critical care area ($p<0.05$). Those who

Table 2. Factors effecting the medical student's willingness to disaster response

	Sex	Semester	Disaster education	TEAMS Project participation	Dependent person in household	Mean±SD	Cronbach
I am willing to join Natural Disasters response If..							
I know my family is safe and cared for	0.432	0.524	0.724	0.811	0.816	4.39±0.92	0.783
I am confident that good lines of communication with my family are in place	0.376	0.528	0.849	0.616	0.512	4.36±0.90	0.777
And if my supervisor works with me	0.084	0.628	0.206	0.278	0.635	4.32±0.86	0.790
I receive appropriate training to deal with the situation	0.383	0.203	0.357	0.308	0.594	4.57±0.68	0.800
I receive regular updates on the progress of the case.	0.286	0.457	0.379	0.110	0.505	4.35±0.84	0.797
I get paid extra for it	**0.012**	0.961	0.972	0.252	**0.015**	3.18±1.33	0.860
Transportation will be provided	0.305	0.753	0.932	0.466	0.464	4.12±1.07	795
							0.846
I am willing to join Natural Disasters response If..							
I know my family is safe and cared for	0.502	0.223	0.929	0.992	0.450	4.26±1.02	0.856
I am confident that good lines of communication with my family are in place	0.229	0.159	0.375	0.347	0.657	4.25±0.92	0.856
My supervisor plays with me	0.052	0.238	0.395	0.120	0.773	4.24±0.95	0.863
I am trained to deal with the situation	0.548	**0.033**	0.937	0.747	0.874	4.33±0.91	0.855
I receive regular updates on the progress of the case	0.617	0.353	0.832	0.576	0.310	4.31±0.89	0.856
Adequate personal protective equipment is provided.	0.459	0.148	0.844	0.769	0.159	4.15±1.13	0.873
I get paid extra for it	0.320	0.667	0.926	0.207	0.710	3.62±1.22	0.875
I can get antivirals (e.g., Tamiflu) for free.	0.299	0.830	0.803	0.420	**0.032**	3.91±1.16	0.861
I can get my vaccinations for free	0.954	0.164	0.500	0.199	0.966	4.09±1.15	0.864
							0.883
I am willing to join Natural Disasters response If..							
I know my family is safe and cared for	0.782	0.678	0.760	0.754	0.919	4.24±1.10	0.822
I am confident that good lines of communication with my family are in place	0.631	0.752	0.499	0.163	0.389	4.22±1.08	0.814
And if my supervisor works with me.	0.554	0.769	0.612	0.934	0.327	4.23±0.98	0.815
I am trained to deal with the situation.	0.788	0.111	0.291	0.916	0.672	4.35±0.96	0.816
I receive regular updates on the development of the incident.	0.418	0.305	0.817	0.634	0.574	4.25±0.98	0.818
I am provided with adequate personal protective equipment.	0.844	0.166	0.688	0.719	0.092	4.03±1.19	0.838
I am paid extra for it	0.223	0.075	0.685	0.269	0.861	3.50±1.38	0.886
Transportation will be provided	0.924	0.746	0.458	0.645	0.297	3.73±1.29	0.854
							0.870

SD: Standard deviation

Table 3. Factors affecting the preferred work area of students during disasters

	Sex			Semester			Dependent person in the family			Disaster training			TEAMS training		
	Male	Female	p	5	6	p	No	Yes	p	No	Yes	p	No	Yes	p
Area															
Emergency room	44	51	0.091	26	69	0.101	78	17	0.558	53	42	**0.002**	69	26	**0.047**
Wards	43	62	0.519	35	70	0.380	87	18	0.428	68	37	0.438	83	22	0.394
Ambulance	9	11	0.449	8	12	0.281	19	1	0.088	11	9	0.320	14	6	0.260
No	4	7	0.496	3	8	0.510	7	4	0.113	8	3	0.441	8	3	0.454
Triage	26	44	0.225	24	46	0.354	57	13	0.515	46	24	0.565	53	17	0.347
Clinical work															
Triage	33	43	0.362	30	46	**0.044**	61	15	0.373	51	25	0.428	61	15	0.318
Trauma	41	51	0.181	31	60	0.324	74	17	0.485	57	34	0.231	69	22	0.304
Critical care	15	15	0.193	13	17	0.107	26	4	0.329	15	15	**0.039**	20	10	0.085
Drug injection	19	37	0.116	22	34	0.106	51	5	**0.022**	35	21	0.327	42	14	0.326
Patient follow-up	35	55	0.281	30	60	0.429	73	17	0.472	57	33	0.262	72	18	0.358
Psychological support	21	44	**0.044**	12	53	**0.002**	53	12	0.531	37	28	**0.043**	48	17	0.208
Community health	18	26	0.550	10	34	0.089	36	8	0.568	23	21	**0.024**	27	17	**0.003**
No clinical support				3	7	0.597	6	4	**0.046**	7	3	0.532	7	3	0.386
Workspace															
Does not want to work	4	6	0.603	6	13	0.596	13	6	0.098	12	7	0.495	13	6	0.217
Ward	49	77	0.190	42	84	0.331	106	20	0.181	85	41	0.265	102	24	0.085
Urgent care	49	55	**0.038**	33	71	0.531	85	19	0.543	64	40	0.104	79	25	0.285
Intensive care support	23	12	**0.001**	17	18	**0.017**	31	4	0.188	24	11	0.425	30	5	0.154
Administrative support															
Patient registration	37	62	0.146	35	64	0.174	82	17	0.443	62	37	0.205	74	25	0.164
Public relations	35	41	0.165	21	55	0.178	62	14	0.529	45	31	0.076	57	19	0.263
Administrative record	29	36	0.297	21	44	0.536	55	10	0.313	36	29	**0.020**	44	21	**0.011**
Porter	25	27	0.153	19	33	0.251	46	6	0.105	34	18	0.544	40	12	0.492
No administrative support	8	19	0.129	9	18	0.516	20	7	0.184	21	6	0.109	22	5	0.320
	71	101		55	117		141	31		113	59		134	38	

feel competent in psychological support and community health services prefer to work in the psychosocial area ($p<0.05$).

Quantitative Analysis

The students were asked about barriers in their volunteering for disaster response, and the answers given were thematized and presented. "Seventy-six students have responded, and 85 different ideas have been proposed".

Barriers to Volunteering

1. Medical Knowledge and Preparedness (n=29)

Sample Answer

"The theoretical information given during the training we received is sufficient, but practical training is insufficient, and disaster response is a field that requires a lot of experience and quick decisions".

2. Psychological Factors and Preparedness (n=22)

a. Known chronic psychological illness (n=6)

b. Personality traits (n=3)

c. Lack of psychological training (n=2)

d. Self-confidence (n=4)

e. Lack of motivation (n=4)

Sample Answer

"Lack of information and lack of psychological support is the biggest factor. In other words, I do not feel that I am in a good

enough psychology to be cold-blooded in that environment if a major incident occurs. To have that psychology, it is necessary to receive continuous training. I could have prepared myself in that way."

3. Family- and Personal-related Problems (n=31)

a. Family-related problems (n=20)

i. Safety issues (n=14)

ii. Communication issues with family (n=6)

b. Personal safety (n=9)

c. Inability to allocate time (n=2)

d. Facilities-funding (n=14)

i. Hospital equipment problems (n=2)

ii. Transport (n=8)

iii. Funding (n=4)

4. Volunteering Related (n=7)

a. Ignorance (n=5)

b. Underappreciation (2)

Sample Answer

"I think I won't get the value and reputation you deserve when you volunteer".

"The idea of getting in the way of situations that more educated people can manage, the lack of a sense of professional competence may prevent me".

5. Intervention Related (n=6)

a. Fear of wrong intervention (n=5)

b. Avoiding legal proceedings (n=1)

Discussion

In disaster situations, the responsibilities of licensed healthcare professionals, such as physicians, nurses, and auxiliary staff, are clearly defined according to their certifications, whereas the role of medical students is less clear.

Student Competence Training and Preparation

In our study, involvement in the TEAMS project was also associated with competence in various disaster skills. Overall, it is encouraging to see that simulations and other experiential learning activities are being used to enhance medical education and improve patient care. These approaches can help bridge the gap between theory and practice and provide opportunities for learners to apply their knowledge and skills in a realistic setting. In a previous study where students functioned as standardized patients during clinical training, all participating interns reported that the activity was both meaningful and educational, either by indicating "agreed" or "strongly agreed". Moreover, 90% of these interns stated that the experience would impact their clinical practice during their first year. These positive results have been consistently observed over time, as demonstrated by a follow-up survey of second-year residents one year later. Specifically, 90% of the residents stated that the activity was meaningful and educational, and 75% reported that the experience had influenced their clinical practice (15). In another standardized patient study, the interns expressed a highly favorable outlook toward the simulation, acknowledging its value in reinforcing the knowledge and skills they had acquired. They highlighted the significance of the post-exercise focus group discussions in solidifying their understanding of the exercise's key concepts and experiences (16).

In our study, students who participated in elective disaster courses or external training programs felt more competent. Preparedness and competence are critical for healthcare professionals during extraordinary events, such as disasters, as they enable them to assume managerial roles and perform their duties professionally (17). Medical schools should consider incorporating disaster medicine and emergency management elements into their required or elective curricula. Completing all or a defined portion of this coursework could become a prerequisite for participation in hospital, clinic, or community response efforts (18). The findings in the literature indicate the importance of healthcare colleges for building students' knowledge, attitudes, and readiness to practice disaster medicine and preparedness before joining the profession (19).

Barriers to Volunteering

Several factors can impact an individual's inclination to participate in volunteer work, including previous training and emergency volunteer experience, perception of the experience's value, belief in duty, financial stability, and access to personal protective equipment. Recruitment of volunteers is a significant challenge, as evidenced by previous emergency planning experience. However, medical students exhibit a keen interest in stepping up to fill this gap, provided that they receive adequate training (9).

Our research has revealed that the primary factors influencing voluntarism are family safety and previous education, whereas financial factors such as salary or transportation exert a minor effect on willingness. These findings underscore the critical role

of imparting the necessary knowledge and skills to students to enhance their self-assurance and ensure the security of their families when soliciting their involvement in volunteer activities. Thus, when developing plans, it is crucial to consider these factors. Moreover, it is imperative to ensure that volunteer students are psychologically prepared for the task at hand.

Locations where students want to work during disasters in hospitals.

In fact, during disasters or public health emergencies, hospitals often need additional personnel to help manage the increased demand for healthcare services. Along with medical aid, medical students can provide administrative support by performing tasks such as answering phone calls, scheduling appointments, and maintaining patient records. In addition, they can assist with coordination, such as ensuring the timely delivery of medical supplies and equipment.

In many cases, medical students may not have direct patient care responsibilities during disasters, but their administrative support roles can still make a significant contribution to the overall healthcare response. By taking on administrative tasks, medical students can help healthcare professionals focus on providing direct care to patients.

In our study, students expressed no hesitation about performing tasks such as transporting patients as part of their duties, and their willingness to participate in a particular area was found to be related to their perceived competency in that area.

Study Limitations

This study is not without limitations, which should be considered when interpreting the results. First, the sample size may not be representative of the wider population, and the findings may not be generalizable. Therefore, caution should be exercised when applying the results to other contexts or populations. Second, the study relied on self-reported data, which may be subject to biases and inaccuracies. It is possible that participants may have overestimated or underestimated their level of competency or motivation. Third, it should be acknowledged that each generation of medical students may have various levels of motivation and willingness to participate in disaster relief efforts. Therefore, it is recommended that similar studies be conducted at regular intervals, such as every five years, to ensure continuity and keep up to date with changes in students' attitudes and perceptions toward disaster response.

Conclusion

Our study demonstrates that students are willing to participate in disaster relief efforts, but they must feel psychologically and medically prepared to increase their motivation. It was found that even actively participating in disaster training programs as trainees or role-players and being in the training environment itself made students feel competent and increased their motivation.

Ethics

Ethics Committee Approval: The research was submitted to the Clinical Research Ethics Committee at University of Health Sciences Turkey, İstanbul Medeniyet University, Göztepe Training and Research Hospital and approved under decision number: 2022/0760, date: 21.12.2022.

Informed Consent: Prior to study, all patients were informed about the nature of the study and a written informed consent was obtained.

Authorship Contributions

Surgical and Medical Practices: G.A.S., K.A., B.A., Concept: G.A.S., G.T.V., K.A., M.K., Design: G.A.S., G.T.V., B.A., Data Collection or Processing: G.A.S., K.A., M.K., Analysis or Interpretation: G.A.S., G.T.V., K.A., B.A., M.K., Literature Search: G.T.V., B.A., M.K., Writing: G.A.S., G.T.V.

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Innovation Skills Assessment and Variation among Healthcare Employees in the Emergency Department: A Cross-sectional Study

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Abstract

Aim: Innovation is vital in emergency departments (EDs), advancing diagnostics, triage, communication, and personalized treatment to save lives and improve patient outcomes. This study aims to assess the self-perceived innovation capacities of employees in the ED of a major quaternary care hospital in Karachi, Pakistan, to establish a baseline and identify areas for improvement.

Materials and Methods: This study employed a descriptive cross-sectional design to assess the innovation skills of employees in the Department of Emergency Medicine and the 24/7 Emergency and Acute Care Service Line at the Aga Khan University Hospital in Karachi, Pakistan. The sample size of 130 employees was determined using non-probability purposive sampling. The study used the Innovation Skills Assessment, a close-ended structured questionnaire, to measure employees' self-perceived strengths and weaknesses in the four pillars of innovation skills. Descriptive statistics and visualizations were used for data analysis. Ethical approval and informed consent were obtained beforehand.

Results: The study showed that employees generally had a positive self-assessment of their innovation skills. There were differences between genders, with males scoring slightly higher. Young employees did not perceive themselves as more innovative, whereas older employees scored lower. Postgraduates and nurses self-assessed higher innovation capacities. Overall, employees showed strengths in idea generation and relationship building but had room for improvement in risk-taking and entrepreneurship.

Conclusion: This study emphasizes the importance of fostering innovation in EDs in low-resource settings to improve patient outcomes. These findings can inform targeted interventions to enhance innovation skills and promote a culture of innovation and entrepreneurship in EDs globally, and in healthcare organizations overall. Further research is needed to explore the relationship between self-assessed and actual innovation performance.

Keywords: Innovation, creativity, entrepreneurship, low and middle income, healthcare delivery, emergency department

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Introduction

Innovation is a critical driver of progress and growth in organizations across various sectors, and the healthcare industry is no exception (1). The ability to innovate allows organizations to develop creative solutions, improve processes, and deliver better outcomes for patients and healthcare systems. Understanding the innovation skills and capacities of employees is essential for fostering a culture of innovation within healthcare organizations (2).

Emergency departments (EDs) play a pivotal role in healthcare delivery, serving as critical entry points for patients in need of immediate medical attention (3). However, globally, EDs face significant limitations that hinder their ability to provide timely and effective care. Overcrowding, resource constraints, and complex patient needs are pervasive challenges, particularly in low- and middle-income countries (LMICs) (4). The convergence of these constraints creates a compelling case for innovation, ideation, and discovery in the ED setting.

In LMICs, where healthcare systems often operate under constrained resources and face unique challenges, fostering a culture of innovation in EDs is imperative. Innovative solutions in these settings can address ED overcrowding by streamlining patient flow, optimizing triage processes, and implementing novel strategies to manage patient surges (5). Additionally, efficiency-driven innovations can help reduce patient wait times, enhance staff communication, and maximize the use of available resources. Creative approaches to patient care and resource management can lead to improved patient outcomes, increased patient satisfaction, and a more resilient and responsive healthcare system (6).

Innovation Skills Assessment (ISA) holds great importance at various levels, including the global, national, and local levels. At the global level, fostering innovation skills is essential for maintaining competitiveness in the global marketplace and driving advancements in healthcare (7). Nationally, ISA can inform policies and strategies aimed at promoting innovation within the healthcare sector, leading to improved healthcare services and outcomes (8). Understanding the innovation skills of employees in specific healthcare settings is crucial for tailoring interventions and initiatives to foster a culture of innovation at the grassroots level (9).

Furthermore, EDs in LMICs frequently develop creative and adaptive practices out of necessity, given the resource constraints and complex patient needs they encounter (10,11). These innovative approaches can inspire and inform ED practices in high-income countries (HICs), where innovation can sometimes be hindered by established processes and a reluctance to deviate from traditional approaches. Thus, the ED setting in LMICs could serve as a model for innovation that applies to EDs in HICs (12,13).

To effectively foster a culture of innovation in EDs, it is crucial to assess and understand the innovation skills and capacities of employees. Such assessments provide insights into employees' strengths and areas for improvement, enabling organizations to design targeted training and development programs to enhance their innovation skills (14). In this regard, tools such as the ISA have been developed to measure various dimensions of innovation skills, such as idea generation, risk-taking behavior, relationship development, and the ability to transform ideas into tangible outcomes (12).

The rationale for conducting an ISA in the ED, Aga Khan University Hospital (AKUH), Karachi, Pakistan, lies in the unique challenges and opportunities posed by low-middle-income healthcare settings. EDs serve as critical gateways to healthcare services, and their efficient functioning is essential for providing timely and effective care to patients in need of immediate medical attention (15).

This study aimed to assess the self-perceived innovation capacities of employees and staff of the Department of Emergency Medicine (DEM) and Acute Care Service Line, AKUH, Karachi, Pakistan. Understanding and enhancing healthcare innovation is increasingly important for delivering high-quality care to patients. Innovation within the ED can lead to improved patient outcomes, more efficient processes, and a better overall healthcare experience. Therefore, we sought to evaluate employees' and staff's abilities in innovative idea generation, risk-taking behavior, relationship development, and the process of pivoting from idea to product. By using the ISA tool, this study sought to obtain valuable insights into the self-perceived innovation skills of employees and identify areas for improvement within the ED of the healthcare setting in Pakistan.

Materials and Methods

Study Design

The study design was a descriptive cross-sectional study. The study population included all employees and staff of the DEM and the 24/7 Emergency and Acute Care Service Line at AKUH, Karachi, Pakistan. The department unites specialties for seamless, holistic care, ensuring effective treatment under one roof for various emergencies. It is 65-bedded in different sections, including but not limited to adult, pediatrics, chest pain unit, observation unit, etc. that collectively cater to close to a hundred thousand patients annually (16).

Sampling Strategy

The study employed non-probability purposive sampling. OpenEpi, version 3, an open-source calculator, was used for sample size calculation. The total number of employees affiliated with the ED, AKUH is 1000 (N): 1000, innovation knowledge and attitude in the population from previous studies (p): 8%+/-5, confidence limits as percentage of 100 (absolute +/- %) (d): 5%, confidence level (%): 95%. The total calculated sample size is 130.

Selection criteria: Inclusion: All employees and staff working and training in the DEM and 24/7 Emergency and Acute Care Service Line at the AKUH. Exclusion: Employees who joined less than 6 months before conducting the study or those who had previously been trained in entrepreneurship and innovation for the organization.

Study site: The study was conducted in the DEM and 24/7 Emergency and Acute Care Service Line at AKUH, Karachi, Pakistan.

Study duration: Our study was conducted for 6 months with data collection conducted as part of the hospital innovation assessment completed over a week in 2021.

Study tool: The ISA tool uses a novel structured questionnaire with closed-ended questions. The ISA was derived from the General Innovation Skills Aptitude Test (GISAT 2.0), which helps organizations assess their innovation skills capacities against their innovation skills needs (17,18). ISA was validated at the ED, AKUH (12,19). The tool assesses individuals, teams, and organizational units across four categories of skills, attitudes, and behaviors that contribute to the capacity to innovate. Critical Creative Innovative Thinking (CCIT) is a platform for developing innovation and entrepreneurship. CCIT has been involved in developing innovation implementation frameworks in the context of LMICs, namely hackathons and innovation fellowships. CCIT is based at AKUH, one of the preeminent healthcare universities in the South Asian region. AKU has set benchmarks and become an industry leader in healthcare service delivery over the years.

The ISA tool comprises four pillars. Pillar 1 focuses on generating ideas and has subcomponents of creativity, problem-solving, and continuous improvement skills. Pillar 2 focuses on calculated risks and being entrepreneurial and has sub-components of risk assessment and risk-taking skills. Pillar 3 focuses on developing and maintaining interpersonal relationships and has subcomponents of relationship-building and communication skills. Pillar 4 focuses on turning ideas into products, processes, services, and implementation skills.

The ISA uses a survey instrument that invites participants to conduct a self-assessment of their perceived strengths and weaknesses across a range of indicators that measure their abilities to act and contribute as well as to manage others in each of these skill categories (Appendix 1). For this study, we only used the self-assessment aspect of the ISA. The survey also captures a range of demographic information about participants, enabling a breadth of analysis of results.

The ISA was developed to provide an understanding of how innovation skills are embodied and used in the pursuit of an organization's operational goals. The ISA helps businesses and individuals better match their innovation skills capacity with their innovation demands by identifying and analyzing the innovation skills found in individuals.

Participants completed the survey instrument individually. For each of the 69 measures in the survey, participants were asked to rank on a five-point scale: (1) the degree to which they feel they demonstrate the described skill, attitude, or behavior; and (2) the degree to which they feel the same skill, attitude, or behavior is important to their job. An assessment of "1" is considered low and an assessment of "5" is considered high.

Ethical Approval

Ethical approval was obtained from the Ethics Review Committee of Aga Khan University (approval no: 2022-1037-21623, date: 23.05.2022). Informed consent was obtained from the study participants. All personal identifiers were anonymized.

Statistical Analysis

Descriptive statistics, including frequencies and percentages, were calculated for categorical variables, whereas the mean and standard deviation were reported for continuous variables. Bar charts were developed for data visualization of categorical variables. Each pillar had scores calculated on a Likert scale of 1 to 5. The score was stratified on the basis of the lowest innovation score (score of 1) to the highest innovation score (score of 5).

Results

One hundred and thirty surveys (approximately 52% coverage) were completed by the employees and staff of the DEM and the 24/7 Emergency and Acute Care Service Line of the AKUH, Karachi, Pakistan. This included a heavier distribution of male employees (57.1%) than female employees (42.9%). Predominantly young employees under the age of 35, although approximately 29% of participants were older than 35. There was a balanced distribution of employees by education level and length of employment in the department. There was a relatively high average assessment of their skills, and there was not a huge difference in self-assessment. Few participants ranked themselves as having a low level of innovation skills, as shown in Table 1.

Table 1. Self-assessment mean score of healthcare employees in the emergency department					
Mean score self-assessment (out of 5)					
Frequency	Percent	Pillar 1: Generating ideas	Pillar 2: Taking calculated risks and being entrepreneurial	Pillar 3: Developing and maintaining interpersonal relationships	Pillar 4: Turning ideas into products, processes and services
130	100	3.9	3.7	4.0	3.9

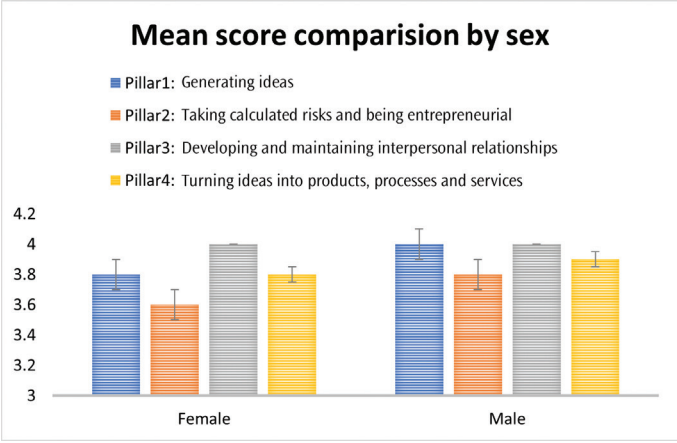

Figure 1. This figure shows the mean scores of self-assessed innovation skills by gender

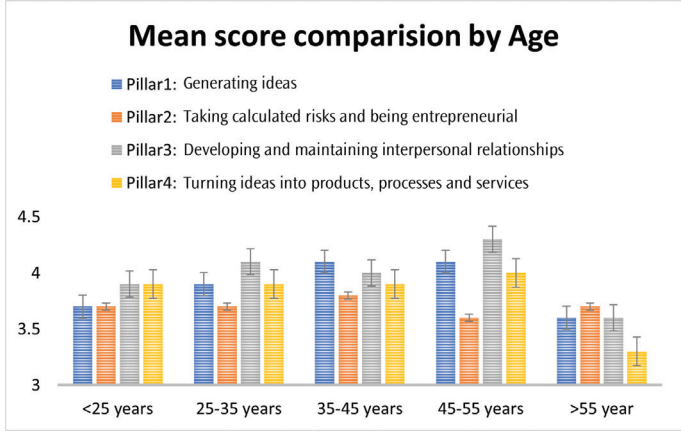

Figure 2. This figure stratifies employees by age and illustrates their self-perceived innovation skills

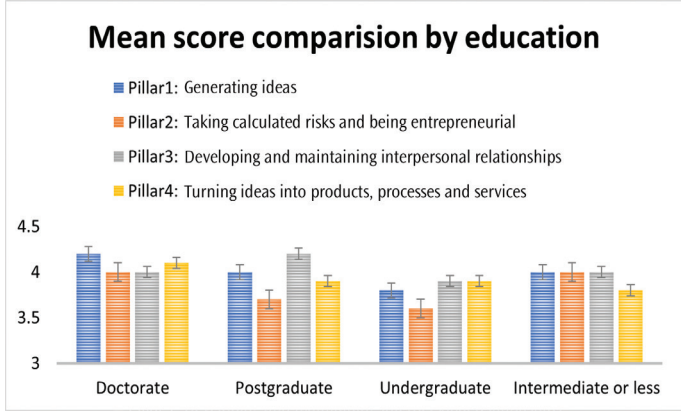

Figure 3. This figure provides insights into self-reported innovation skills based on the respondent's level of education

The results from the mean comparison of skills assessment by gender (Figure 1) suggested that although males generally scored themselves higher across the three categories of innovations skills, the difference between the two genders was not substantially different. Both male and female employees scored lowest on their abilities to take calculated risks and being entrepreneurial.

For skills assessment stratified by age (Figure 2), employees under 25 years of age did not perceive themselves to be more innovative than their colleagues in other age groups. Employees aged 45-55 scored themselves higher than most of their younger colleagues on pillars 1 and 3. However, they self-assessed being less entrepreneurial. Employees aged 55 years or above scored significantly lower on almost all innovation parameters than their younger colleagues.

Stratifying by the level of education (Figure 3), we found that postgraduates self-reported the highest levels of relationship-building and communication skills. Scores in Pillar 4 increased steadily by individuals at each higher level of education. Employees having completed intermediate education or less self-assessed 3 of the 4 pillars for innovation skills to be comparable or sometimes higher than their more highly educated colleagues. Employees with an undergraduate degree reported the lowest innovation self-assessment scores compared with the other groups.

Stratifying per employee service length (Figure 4), revealed that staff members with less than one year of service experience did not perceive themselves to be more innovative than their colleagues having longer service. Employees with more than ten years of service reported strong skills in creativity, problem-solving, and risk assessment. However, they were less confident about their relationship management skills.

Stratifying per professional cadre (Figure 5) revealed that nurses self-assessed their innovation capacities higher than doctors and other professionals across all pillars of the ISA. Doctors were found

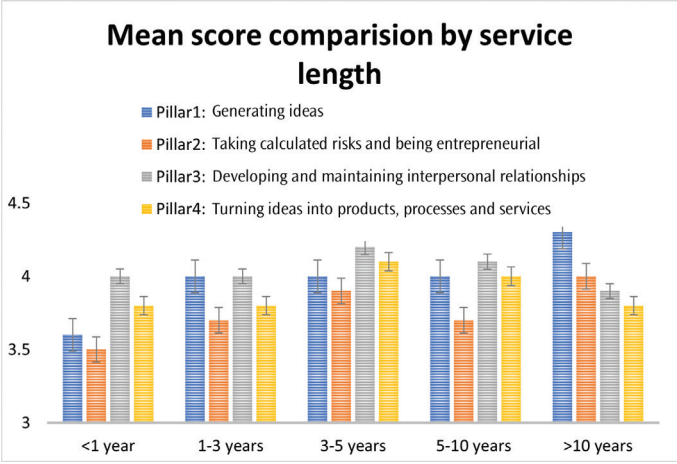

Figure 4. This figure categorizes employees based on their service length and reveals their self-perceived innovation skills

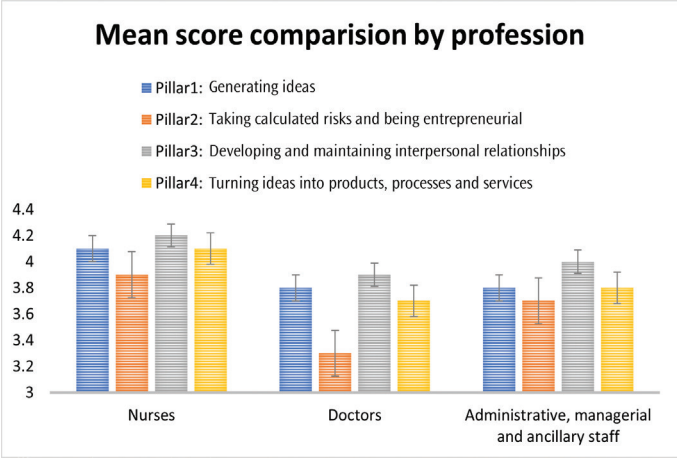

Figure 5. This figure highlights differences in self-assessed innovation capacities among various professional cadres

to be considerably low in their pillar 2 skills (taking calculated risks and being entrepreneurial) while also self-ranking lower in other pillars compared with nurses, administrative, managerial, and ancillary staff.

Discussion

The ED is a dynamic and high-pressure environment that requires "smart" approaches for efficient patient care while maintaining utmost safety. ED throughput demands quick thinking, faster decision-making, and streamlined processes to handle the constant influx of patients with diverse and often critical medical needs (20). The ISA tool is crucial for understanding the mindsets of various cadres within the ED and assessing their innovation capacities. Employees of the ED, AKUH, Karachi, Pakistan, were found to have relatively high self-assessment of their innovation, creativity, and entrepreneurship skills (21).

The analysis of self-assessed innovation skills by gender indicated that male employees generally scored higher across the three categories of innovation skills. However, the difference between the genders was not substantially different. Both male and female employees rated themselves lowest in their abilities to take calculated risks and being entrepreneurial. These findings suggest the need for targeted interventions and training programs to encourage risk-taking and foster an entrepreneurial mindset among employees of both genders (22,23).

Interestingly, younger employees (under 25 years old) did not perceive themselves to be more innovative than their peers in other age groups, contrasting expectations. Employees aged 45-55 self-assessed higher on idea generation and relationship development skills than their younger colleagues but scored lower on being entrepreneurial. Employees aged 55 or above scored significantly lower on almost all innovation parameters compared with their younger counterparts. They have a wealth of experience and know-how. However, when it comes to being entrepreneurial and taking bold risks, they are not as confident. This could be because they have more financial responsibilities, such as mortgages and family expenses, making them less inclined to take risks that could jeopardize their stability. It might also be because the organizations in which they work may not encourage or reward entrepreneurial behavior. Older employees have experience and relationship skills, but they might need a nudge to be more daring in their approach, which is essential for innovation and growth. These findings emphasize the importance of leveraging the strengths and experiences of employees across different age groups to foster innovation in the workplace (24).

The results from the skill assessment mean comparison by education level indicate that postgraduates reported the highest levels of relationship-building and communication skills. Additionally, as the level of education increased, scores in turning ideas into products and processes also increased. Surprisingly, employees with intermediate education or less self-assessed their innovation skills to be comparable to or even higher than their more highly educated colleagues in three out of the four pillars. This highlights the potential of individuals with diverse educational backgrounds to contribute to innovation within the department (25,26). The ED brings together professionals from various disciplines, including doctors, nurses, paramedics, administrative staff, and others, each with unique expertise and perspectives. This inter-disciplinary collaboration fosters a diverse and rich pool of ideas, enabling the cross-pollination of innovative solutions and problem-solving approaches (27).

The findings from the skills assessment mean comparison by length of service suggest that employees with less than one year

of service did not perceive themselves to be more innovative than their colleagues with longer service. This lack of perceived innovation among new employees can be attributed to the formidable challenges associated with transitioning into a new work environment. These individuals may be in the process of acclimating to their roles, company culture, and the intricacies of their new positions, leaving them with less bandwidth to actively engage in innovative thinking. On the other hand, employees with more than ten years of service reported strong skills in creativity, problem-solving, and risk assessment, likely because of their accumulated experience. However, they expressed less confidence in their relationship management skills. These results suggest the need for continuous professional development programs to enhance the relationship management skills of long-serving employees (28).

The results from the skills assessment mean score comparison by profession show that nurses in the ED had higher self-assessed innovation capacities than doctors and other professionals, indicating their unique and crucial role in patient care innovation. The lower scores for doctors in risk-taking and entrepreneurship may be attributed to the perception that their roles necessitate strict adherence to standardized care, potentially inhibiting their inclination to innovate. This emphasizes the importance of cultivating innovation skills among doctors and encouraging a culture that supports risk-taking and entrepreneurial thinking within the healthcare profession to enhance patient care and drive progress in the field (29,30).

These insights can be extrapolated to other healthcare areas. Implementing the ISA tool in different hospital domains can establish innovation baselines, fostering continuous improvement. ISA's potential for benchmarking enables identifying best practices and driving positive change. Its scalability offers an opportunity to enhance global healthcare innovation by addressing post-pandemic challenges and financial constraints for improved patient outcomes and efficient healthcare delivery (31,32).

These findings have significant implications for the development of targeted interventions, training programs, and policies that foster an innovative culture within the department. Future research should explore the relationship between self-assessed innovation skills and actual performance while considering additional factors influencing healthcare innovation. As the next step, the potential for scaling this approach lies in the creation of low-cost, app-based innovation dashboards with real-time updates for benchmarking and driving continuous improvement. This scalable concept holds promise globally, including in HICs, where it can address financial crises, post-pandemic scenarios, and healthcare challenges. Widely implementing the ISA can elevate healthcare innovation, enhance patient outcomes, and improve overall efficiency on a global scale.

Study Limitations

Our study is the first comprehensive assessment of its kind for innovation skills using the ISA tool for any ED globally. It has low resource utilization yet is rich in meaningful data, is administered online, has simple data analytics, and can be translated into other languages, allowing for a detailed understanding of the various dimensions of innovation given the dynamics of the ED. The balanced distribution of employees across demographic and professional factors contributes to the generalizability of the findings within the department. Additionally, conducting the study in a specific local context in Pakistan provides insights into innovation skills within a unique healthcare setting.

The self-assessed nature of the data introduces the potential for selection and reporting bias, as individuals may overestimate or underestimate their innovation skills. The study's focus on a single ED of a tertiary care hospital limits the generalizability of the findings to other healthcare contexts. Moreover, the absence of a comparison group hinders benchmarking and external validation of the self-assessments. Future research should consider incorporating multiple methods and expanding the study to include a larger sample size and diverse healthcare departments to enhance the robustness and generalizability of the findings.

Conclusion

The findings highlight the importance of fostering a culture of innovation within the healthcare sector, specifically in the ED, to improve patient outcomes. Surprisingly, younger employees did not perceive themselves as more innovative, challenging preconceptions, while older employees revealed room for improvement in entrepreneurial thinking. Education level played a role in relationship skills, showcasing the diverse contributions of individuals with varying educational backgrounds. Further research to validate self-assessments and understand the link between innovation skills and performance is crucial. Embracing innovation brings transformative changes to both low-resource and high-income healthcare settings.

Ethics

Ethics Committee Approval: Ethical approval was obtained from the Ethics Review Committee of Aga Khan University (approval no: 2022-1037-21623, date: 23.05.2022).

Informed Consent: Informed consent was obtained from the study participants.

Authorship Contributions

Concept: D.M., W.F., A.M., Design: D.M., W.F., A.M., Data Collection or Processing: H.N.T., A.R., A.M., Analysis or Interpretation: H.N.T., A.R., Z.A.A., D.M., W.F., A.M., Literature Search: Z.A.A., A.M., Writing: H.N.T., Z.A.A., A.M.

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Appendix 1. Survey instrument

PILLAR #1: GENERATING IDEAS

Low → High	(Circle the number indicating your choice)	Low → High
SELF-ASSESSMENT	**Act and Contribute**	**JOB ASSESSMENT**
1 2 3 4 5	You look for new ways to create value in products, processes, services	1 2 3 4 5
1 2 3 4 5	You are good at identifying problems and potential solutions	1 2 3 4 5
1 2 3 4 5	You question assumptions and recognize opportunities for change	1 2 3 4 5
1 2 3 4 5	You like to seek different points of view	1 2 3 4 5
1 2 3 4 5	You are adaptable and flexible	1 2 3 4 5
1 2 3 4 5	You like to rethink the way things are done	1 2 3 4 5
1 2 3 4 5	You approach challenges creatively	1 2 3 4 5
1 2 3 4 5	You look for surprising connections	1 2 3 4 5
1 2 3 4 5	You put forward your own ideas with confidence	1 2 3 4 5
1 2 3 4 5	You like to suggest alternative ways to achieve goals	1 2 3 4 5
1 2 3 4 5	You evaluate solutions so as to make recommendations or decisions	1 2 3 4 5

SELF-ASSESSMENT	Manage and Support Others	JOB ASSESSMENT
1 2 3 4 5	You trust other people's ideas and actions	1 2 3 4 5
1 2 3 4 5	You nurture and promote creativity and inventiveness	1 2 3 4 5
1 2 3 4 5	You like to question and challenge the way things operate	1 2 3 4 5
1 2 3 4 5	You have a vision of where you (and your organization) want to go	1 2 3 4 5
1 2 3 4 5	You are open to new ideas and different ways of doing things	1 2 3 4 5
1 2 3 4 5	You keep track of your success and failures to find ways to improve	1 2 3 4 5
1 2 3 4 5	You recognize and reward original ideas and ideas for improvement	1 2 3 4 5

PILLAR #2: TAKING CALCULATED RISKS AND BEING ENTREPRENEURIAL

Low → High	(Circle the number indicating your choice)	Low → High
SELF-ASSESSMENT	**Act and Contribute**	**JOB ASSESSMENT**
1 2 3 4 5	You are comfortable pursuing new opportunities	1 2 3 4 5
1 2 3 4 5	You are able to identify, quantify and qualify a risk	1 2 3 4 5
1 2 3 4 5	You are comfortable taking appropriate risks	1 2 3 4 5
1 2 3 4 5	You identify, control, and avoid dangers and threats	1 2 3 4 5
1 2 3 4 5	You stay focused on what you are trying to achieve when suggesting alternative ways to get a job done	1 2 3 4 5
1 2 3 4 5	You can see your risk-taking paying off	1 2 3 4 5
1 2 3 4 5	You learn from your experiences and are not afraid to make mistakes	1 2 3 4 5
1 2 3 4 5	You are willing to experiment with new ideas	1 2 3 4 5
1 2 3 4 5	You can take actions without knowing every outcome or consequence	1 2 3 4 5
1 2 3 4 5	You have confidence to apply skills in new and unfamiliar situations	1 2 3 4 5

SELF-ASSESSMENT	Manage and Support Others	JOB ASSESSMENT
1 2 3 4 5	You encourage individuals and teams to bring forward new ideas	1 2 3 4 5
1 2 3 4 5	You support risk by monitoring and evaluating decisions and actions	1 2 3 4 5
1 2 3 4 5	You are resilient in facing setbacks, mistakes, and potential mistakes	1 2 3 4 5
1 2 3 4 5	You do not penalize unforeseeable mistakes	1 2 3 4 5
1 2 3 4 5	You are accepting of failures and willing to learn from them	1 2 3 4 5
1 2 3 4 5	You recognize and reward the pursuit of new opportunities	1 2 3 4 5

PILLAR #3: DEVELOPING AND MAINTAINING INTERPERSONAL RELATIONSHIPS

Low → High	(Circle the number indicating your choice)	Low → High
SELF-ASSESSMENT	**Act and Contribute**	**JOB ASSESSMENT**
1 2 3 4 5	You engage others to make use of their skills, knowledge, and abilities	1 2 3 4 5
1 2 3 4 5	You build and maintain relationships inside and outside of your organization, and with people from diverse backgrounds	1 2 3 4 5
1 2 3 4 5	You recognize that relationships are reciprocal	1 2 3 4 5
1 2 3 4 5	You understand and work within the dynamics of a group	1 2 3 4 5
1 2 3 4 5	You share information and expertise with colleagues and partners	1 2 3 4 5
1 2 3 4 5	You respect/support ideas, approaches, and contributions of others	1 2 3 4 5
1 2 3 4 5	You listen to and value diverse opinions and perspectives	1 2 3 4 5
1 2 3 4 5	You accept and provide feedback in a constructive manner	1 2 3 4 5
1 2 3 4 5	You overcome barriers among people that may impede results	1 2 3 4 5

SELF-ASSESSMENT	**Manage and Support Others**	**JOB ASSESSMENT**
1 2 3 4 5	You encourage, mentor and coach others to share ideas freely	1 2 3 4 5
1 2 3 4 5	You involve others by delegating responsibility and supporting efforts	1 2 3 4 5
1 2 3 4 5	You make it easy for people to collaborate and deliver new solutions	1 2 3 4 5
1 2 3 4 5	You allocate resources for networking and sharing of ideas and skills	1 2 3 4 5
1 2 3 4 5	You promote personal development in others	1 2 3 4 5
1 2 3 4 5	You provide guidance, honest praise and constructive feedback	1 2 3 4 5
1 2 3 4 5	You recognize and reward the success of individuals and teams	1 2 3 4 5

PILLAR #4: TURNING IDEAS INTO PRODUCTS, PROCESSES AND SERVICES

Low → High	(Circle the number indicating your choice)	Low → High
SELF-ASSESSMENT	**Act and Contribute**	**JOB ASSESSMENT**
1 2 3 4 5	You set realistic goals and priorities	1 2 3 4 5
1 2 3 4 5	You access and apply knowledge and skills from many sources	1 2 3 4 5
1 2 3 4 5	You show ingenuity in devising, planning and implementing solutions	1 2 3 4 5
1 2 3 4 5	You plan for contingencies and are ready with alternative strategies	1 2 3 4 5
1 2 3 4 5	You adapt to changing requirements	1 2 3 4 5
1 2 3 4 5	You use the right tools or technologies to complete tasks and projects	1 2 3 4 5
1 2 3 4 5	You are tenacious—you show initiative and commitment	1 2 3 4 5
1 2 3 4 5	You accept feedback and are willing to learn from your mistakes	1 2 3 4 5
1 2 3 4 5	You check to see if a solution works and look for improvements	1 2 3 4 5
1 2 3 4 5	You use metrics to measure and show the value of a solution	1 2 3 4 5
1 2 3 4 5	You are accountable for what you and your group do	1 2 3 4 5

SELF-ASSESSMENT	**Manage and Support Others**	**JOB ASSESSMENT**
1 2 3 4 5	You adopt and promote a “can do” attitude	1 2 3 4 5
1 2 3 4 5	You understand how change affects the performance of organizations	1 2 3 4 5
1 2 3 4 5	You are proactive in leading and responding to change	1 2 3 4 5
1 2 3 4 5	You empower others to make decisions	1 2 3 4 5
1 2 3 4 5	You are tolerant of mistakes when trying out new ideas	1 2 3 4 5
1 2 3 4 5	You value, support, and reward initiative	1 2 3 4 5
1 2 3 4 5	You celebratenew products, services, processes, strategies, etc.	1 2 3 4 5
1 2 3 4 5	You measure impacts of solutions on organizational performance	1 2 3 4 5

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Predicting Intubation in COVID-19 Patients by the ROX Index Method

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Abstract

Aim: To evaluate the diagnostic accuracy of the ROX index for predicting intubation in Coronavirus disease-2019 (COVID-19) patients receiving high nasal flow cannula (HNFC) and to underline the risk and association of intubation with pre-existing comorbidities in COVID-19 patients.

Materials and Methods: A multicenter prospective cohort study was conducted on 123 patients suffering from severe COVID-19 disease from March 2020 to December 2021. The ROX index was calculated at baseline, 2nd, 6th and 12th hour of HNFC and patients were followed for the primary outcome, i.e., invasive ventilation (IV). The diagnostic performance of ROX indices for primary outcome and risk of comorbidity were estimated.

Results: The primary outcome occurred in 49 (39%) patients, most of whom were elderly and suffering from underlying conditions. The ROX index was significantly associated with poor outcome, whereas the best predictive value (sensitivity; 91.8%, area under the curve: 0.905) for IV was found for 12th hour of HNFC. Furthermore, the risk of IV increases with comorbidity.

Conclusion: According to our findings, we speculate that the ROX index could predict the occurrence of adverse events. Moreover, we further suggest that the data regarding comorbidities are valuable in assessing the risk of IV in COVID-19 patients.

Keywords: ROX index, COVID-19, high nasal flow canula

Introduction

Nearly 14% of Coronavirus disease-2019 (COVID-19) patients suffer from acute hypoxic respiratory failure (ARF), which is usually managed by a high nasal flow cannula (HNFC) to restore oxygenation (1). HNFC is a heated circuit that delivers humidified air via a non-invasive nasal cannula. Despite success, a subset of patients on HNFC become non-responders eventually requiring an invasive approach of intubation or mechanical ventilation (MV) (2).

From the very beginning of the COVID-19 pandemic, emergency physicians have been struggling, especially in resource constraint set-ups, to deal with the overwhelming number of COVID-19 patients requiring MV for survival (3,4). Therefore, the challenge is to find new ways to identify patients who are likely to end up in HNFC failure and be weaned by MV (2). In this context, some authors have recently evaluated the ROX index as a predictor of intubation in COVID-19 patients; however, the validation of this tool is subject to further studies (5,6).

The ROX algorithm measures the ratio of oxygen saturation (FiO_2) and predicts the need to intubate and mechanically ventilate patients with ARF. It was first described in 2016 by Roca et al. (5) in a multicenter prospective cohort of 157 patients with ARF on HFNC. The authors found that score <4.88, measured at 12th hour after the onset of HFNC showed significant risk for the need of invasive treatment (5). These results were also supported by a subsequent study analyzing the diagnostic accuracy of the ROX index in 191 patients with pneumonia treated with HFNC (7). In addition, the superiority of ROX for predicting invasive treatment was reported by a large-scale FLORALI cohort (8).

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These findings indicate that the ROX index is an easy-to-use clinical method that could act as an early warning system for HNFC failure in COVID-19-related ARF patients. Additionally, early warning for invasive treatment approaches would allow hospitals to meet the unprecedented demand for ventilators during the COVID-19 surge by implementing an effective resource allocation strategy, thus saving many lives. To the best of our knowledge, the ROX index has not yet been applied in COVID-19 patients; hence, we aimed to validate the diagnostic accuracy of the ROX algorithm for predicting HNFC failure and the need for invasive ventilation (IV) in COVID-19 patients. Furthermore, our secondary goal was to assess the risk of invasive management in patients with different comorbidities.

Materials and Methods

Study Design and Setting

A multicenter prospective cohort was designed after obtaining ethical approval from the Ziauddin University Ethics Review Committee (ERC#1701219FHPAT, date: 10.02.2020). Informed consent was obtained from all participants. The subjects were recently admitted and treated for COVID-19 between March 2020 and December 2021 in critical care units of six major tertiary care setups in district east, Karachi, Pakistan. The demographic data were obtained from the principal investigator via a research questionnaire, while the medical records and history were used to determine pre-existing conditions.

Patients

A total of 123 new cases with laboratory confirmed COVID-19 infection were selected for investigation. The selection procedure was carried out using the non-probability consecutive sampling technique. We employed very stringent inclusion criteria and recruited only those patients who were subjected to HNFC on admission based on their oxygenation parameters. The patients were placed on HFNC if SpO_2 fell below 93% and FiO_2~30% with evident respiratory distress despite being oxygenated. For HFNC, FiO_2 to sustain SpO_2 above 92% was initiated at a flow rate of 50 to 60 L/min. For the protective measures, a heat moisture exchange filter was used between the nasal cannula and the non-IV (NIV) device, and a protective pad was applied on the nasal area to avoid skin wear and tear. The exclusion criteria were based on all those who were already intubated or mechanically ventilated on admission, those on conventional oxygen therapy, and patients with mild to moderate COVID-19 disease.

The patients were followed for intubation or MV until discharge from the hospital or death. The criteria for intubation on HNFC subjects were FiO_2 >60% and signs of respiratory distress or other organic dysfunctions. The intubated patients were reassessed every 30 to 60 min for improvement in ventilatory parameters. To minimize microbial transmission, a high-efficiency particulate arrestable filter was employed on the exhalation output of the MV.

Procedure

The ROX parameters SpO_2, FiO_2, and respiratory rate were measured and documented at time 0, i.e., on admission and at the 2nd, 6th, and 12th hour after the onset of HFNC. The final ROX score was calculated for each of the aforementioned hours using the formula: SpO_2/FiO_2*, %/respiratory rate, breaths/min. The ROX index was interpreted as described by Blez et al. (9) and Roca et al. (5) i.e. ≥4.88 for lower risk of intubation while <4.88 suggest high risk of HNFC failure.

Statistical Analysis

Data were assessed for normality using the Shapiro-Wilk test. For analysis, we developed the control and case groups on the basis of the outcome. The control group comprised patients maintained on HNFC, and the case group comprised patients with the outcome of HNFC failure requiring IV (i.e., intubation/MV). Continuous variables are presented in terms of median or interquartile ranges, and categorical variables are presented as frequencies (%) and absolute numbers (n). The sensitivity, specificity, positive predictive value, and negative predictive value were calculated to determine the diagnostic accuracy of the ROX index at time 0 (on admission), 2nd, 6th, and 12th hour, while the strength of association was assessed by Fisher's exact test. The risk of invasive treatment in patients with comorbidities was analyzed, and the statistical power of significance was estimated for each independent variable. All statistical analyses were performed using MedCalc software version 20, and p value ≤0.05 was considered statistically significant.

Results

Of the 123-COVID-19 cohorts, 49 (39%) patients suffered failure of HFNC and were classified as cases. All these cases were managed by endotracheal intubation (ETI) and MV. The overall mortality was 19 (15%)in the case group. Our baseline data indicated that there were more males (73%) than females (27%) in our study. The age bracket for all subjects ranged from 33 to 84 years, and the median age was recorded as 66 years.

On the analysis of ROX index, we found the range in the overall population at time 0 was 3.5-5.7, at 2nd hour was 3.2-6.5, at 6th hour was 3.0-8.2, and at the 12th hour was 2.9-10.1. The medians for these ranges were 3.80, 4.90, 4.80, and 5.0 for 0, 2, 6, and 12 h readings, respectively. Moreover, the ROX data monitored at different hours (0, 2, 6 and 12) were all statistically related to the

cases. We observed a consistent rise in the diagnostic accuracy of the ROX index to predict IV at subsequent time intervals. The highest diagnostic value of the ROX index was recorded for 12th hour with a sensitivity of 91.8% and a specificity of 89.1%. The validity indices were also supported by receiver operating curve analysis with the maximum area under the curve (AUC; 0.905) for the ROX index at 12th hour (Figure 1). Table 1 shows the diagnostic value of ROX index in discriminating HFNC failure at 0, 2nd, 6th and 12th hour.

Our clinical data showed that most of the studied patients had some comorbidity (83%). The main comorbidities associated with intubation in COVID-19 patients were increased age, hypertension, diabetes mellitus, chronic kidney disease, asthma, and chronic obstructive pulmonary disease. Besides cardiovascular diseases and malignancy, all comorbidities showed a significant increase in the risk for the need for invasive treatment at 95% confidence interval (CI). However, chronic kidney disease showed the highest risk (2.52, 95% CI: 1.75-3.63) for the invasive approach. Table 2 presents the risk estimates for invasive oxygenation and the association of comorbidities.

Discussion

HNFC has gained popularity in recent years as a first-line treatment for COVID-19-related ARF. Owing to the positive impact of HNFC on gas exchange parameters, masking of the deteriorating clinical picture has become increasingly common, resulting in delayed decision for interventional treatments. As a consequence, fatal outcomes are often encountered in critically ill COVID-19 patients (10). Hence, early warning tools for the indication of failure of NIV have been an area of research interest. The ROX index is one such tools that has shown promising results (6).

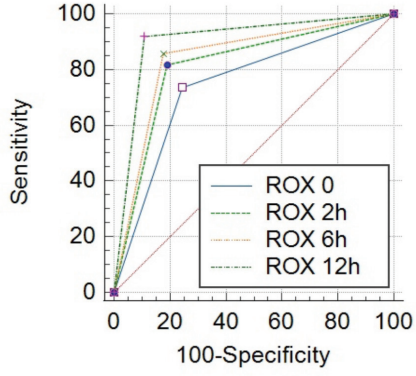

Figure 1. Receiver operating curve depicting sensitivity points of ROX index to predict intubation at time 0 (blue), 2nd hour (green), 6th hour (orange) and 12th hour (dark green) from the onset of high nasal flow cannula

The ROX index was first described by Roca et al. (5) in the pre-COVID era as a method to predict HNFC failure in pneumonia patients. The authors recommended that a score below 4.88 is an indication for a high risk of intubation, whereas a score higher than 4.88 suggests a good outcome. Subsequently, a multiethnic study from Europe successfully validated the ROX score of 4.88 as a cut-off to predict outcome (11). Both investigators used readings taken at 0, 2, 6, and 12 h from the start of conventional NIV treatment to calculate final ROX scores (5,11). In contrast, Rodriguez et al. (12) calculated ROX scores for intervals up to 48 h and found higher values as cut-off values for stratification of HFNC patients.

Among early COVID-19 studies, Blez et al. (9) evaluated the diagnostic performance of the ROX index using a predefined cut-off >4.88 for success of HNFC in COVID-19 patients and found 81% sensitivity. In later studies, Suliman et al. (13) documented that the ROX index is an independent predictor of IV with 90.2% sensitivity and 75% specificity in patients suffering from severe COVID-19 infection on admission. Additionally, in a multicenter study, Vega et al. (6) reported that the ROX index at 12 h is the best predictor of intubation or MV (AUC of 0.7916) in COVID-19 patients; however, the study found a higher threshold value (<5.99) for stratification and suggested that a cut-off of less than 4.88 could be used as an indicator for HNFC failure in non-COVID patients. In another study, Luis et al. (14) found that ROX index 4.88 both at 2 and 12 h increased the risk of ventilatory failure and poor outcome. Nonetheless, a significant statistical relationship between the ROX index and intubation was concordant in all studies, indicating the external validity of ROX at any time interval during management (6,9,13,14).

In this study, we used a pre-described cut-off <4.88 as the predictor of invasive treatment and found good accuracy of the ROX index for discriminating HNFC failure in COVID-19 patients. This finding is consistent with those of Vega et al. (6) and Luis et al. (14). However, in a later analysis, the authors reported a higher threshold for discrimination than that described earlier (6). Nevertheless, investigators included patients with moderate ARF who were treated outside the intensive care unit (ICU), which might be the reason for high ROX scores contributing to an elevated threshold (6). Also, similar to Vega et al. (6), we noted greater diagnostic performance of ROX at 12th and 6th hour. As most intubation occurs after 12 h of HNFC, we suggest that the ROX index could be an ideal tool to assess the need for IV in COVID-19 patients.

In addition to diagnostic performance, our secondary goal was to assess the likelihood of intubation with comorbidities. We found that underlying hypertension and diabetes were the leading conditions in our series. Similar observations were

Table 1. Diagnostic performance of ROX index to predict invasive ventilation at different time intervals						
ROX index (<4.88)*	**p value‡**	**Sensitivity (%)**	**Specificity (%)**	**PPV (%)**	**NPV (%)**	**AUC†**
0 h	0.001	73.4	75.6	25.1	96.2	0.746
2 h	0.001	81.6	81	32.4	97.5	0.814
6 h	0.001	85.7	82.4	35.1	98.1	0.841
12 h	0.001	91.8	89.1	48.5	98.9	0.905

*High-risk of intubation, ‡Fisher's exact test, †Area under the curve.
PPV: Positive predictive value, NPV: Negative predictive value

Table 2. Risk estimates of comorbidities for invasive ventilation			
Comorbid	**Risk***	**95% CI**	**p value‡**
Age (33-84 years)	2.38	1.28-4.44	0.002
Hypertension (n=31)	2.04	1.37-3.04	0.002
Diabetes (n=24)	1.82	1.20-2.74	0.019
Chronic kidney disease (n=23)	2.52	1.75-3.63	0.001
Chronic liver disease (n=19)	1.58	1.00-2.50	0.125
Asthma (n=19)	1.97	1.32-2.96	0.010
Cardiovascular disease (n=14)	1.51	0.90-2.54	0.245
Chronic obstructive pulmonary disease (n=9)	2.11	1.38-3.22	0.029
Pulmonary fibrosis (n=7)	1.88	1.11-3.17	0.114
Malignancy (n=5)	1.00	0.33-3.00	1.00

*Risk for intubation, ‡Fisher's exact test.
CI: Confidence interval

made in an early Chinese study and a meta-analysis estimating the prevalence of comorbidities in COVID-19 patients (15,16). We also noted that most patients who required IV belonged to the elderly age group. In general, older age is a predictor of adverse outcomes in viral infections, and this might be the case in COVID-19 disease (17).

Our statistical data indicated that older adults with different underlying health conditions are at a higher risk of severe COVID-19 outcomes. In concordance, the preliminary literature also showed that almost 70% of the COVID-19 patients on ventilator had some form of comorbidity (18). In addition, pooled data from the United States suggested that people with underlying health conditions have significant odds of developing a severe form of COVID-19 disease (19). Among the underlying conditions, we found that almost all comorbidities were significantly associated with a high risk of intubation; however, chronic kidney disease poses the greatest threat to intubation during hospitalization. In contrast, most authors found that the risk of invasive management is highest in diabetic patients (16). We suggest two reasons for our observations. First, patients with end-stage renal disease are typically immunocompromised, leading to infections with severe outcomes. Alternatively, the low prevalence of chronic renal conditions in previous cohorts might have contributed to this discrepancy.

Study Limitations

This research has both strengths and limitations. To the best of our knowledge, this is the first study in Pakistan to evaluate the ROX index in a clinical setting, providing hospitals with an opportunity to implement a simple and non-invasive method for better care and resource allocation. Moreover, the multicentric design allows diverse strata of population to be analyzed in this cohort. Furthermore, we followed prospective sampling, which has the advantage of examining multiple effects and is also tailored to control confounders, thus minimizing bias. Another important aspect of this study is to assess the impact of comorbidity on the risk of invasive treatment modality besides validating the ROX index.

In addition, the present research has some limitations. First, apart from the ETI, other invasive approaches such as; orotracheal intubation were not considered as these modalities are less frequently offered in ICUs and none of the subjects underwent any of these procedures. Second, we characterized the comorbidities based on history and recent medical records; however, fresh investigations to analyze the current status of disease was not done. In addition, we did not inquire about the duration of underlying diseases for correlation. Lastly, the sample size could have increased further to provide more external validity to our observations.

Conclusion

In summary, this multicenter study indicated that the ROX index could prove vital in guiding clinical decisions regarding IV in critically ill COVID-19 patients. Indeed, our observations suggested that ROX score especially at 12th and 6th hour from the start of HNFC, could anticipate the need for invasive management with high accuracy. Furthermore, pre-existing comorbidities have a significant impact on adverse outcomes in COVID-19 patients; however, renal diseases, hypertension, and diabetes are the major risk factors for clinical deterioration requiring IV.

Ethics

Ethics Committee Approval: A multicenter prospective cohort was designed after obtaining ethical approval from the Ziauddin University Ethics Review Committee (ERC#1701219FHPAT, date: 10.02.2020).

Informed Consent: Informed consent was obtained from the study participants.

Authorship Contributions

Surgical and Medical Practices - Concept - Design - Data Collection or Processing - Analysis or Interpretation - Literature Search - Writing: N.T., S.H., F.A.B.

Conflict of Interest: No conflict of interest was declared by the authors.

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Examination of Pediatric Trauma Patients Admitted to the Emergency Department

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Abstract

Aim: The aim of this study was to analyze the demographic and laboratory data of pediatric trauma patients admitted to the emergency department.

Materials and Methods: Our study was conducted by retrospectively analyzing the files of 573 patients from the computer registry system of pediatric trauma cases aged between 0 and 16. In addition, information such as age and gender of the patients, monthly admissions, mechanism of trauma, the place where the trauma occurred, the consultations requested, the services where the patients were followed, the body parts exposed to the trauma, radiological and laboratory findings, and the treatments given were specified.

Results: The most common mechanisms among trauma etiologies were falling and impact on pediatric traumas. Head and neck injuries occurred first when body parts exposed to trauma were examined. It was determined that head and neck injuries increased as age decreased. It was found that the frequency of abdominal trauma increased as age decreased, and those with abdominal injury had lower hemoglobin and hematocrit values and higher alanine aminotransferase and aspartate aminotransferase values compared with those without abdominal injuries.

Conclusion: It has been determined that in terms of the incidence of pediatric traumas, there were different etiological causes and trauma areas, their frequency varied seasonally, and a good evaluation of the blood tests was critical in the assessment and follow-up of patients and to avoid missing some injuries.

Keywords: Emergency, etiology, laboratory, paediatrics, trauma

Introduction

Trauma is one of the main causes of death in developed countries worldwide. Trauma, which is the leading cause of death in children, accounts for approximately 50% of all childhood deaths (1). It has been reported that 30% of early deaths of children with trauma can be prevented with an early evaluation and treatment (2).

There are significant anatomical, physiological, and psychological differences between adult and pediatric patient populations. The frequency and types of accidents vary with the age of the children (3). The main causes of trauma in children are traffic accidents, falls, and bicycle accidents. One-third of important injuries in children occur in the home environment (1). In infants and young children, injuries most frequently occur at home (4). Additionally, traumas can cause psychological problems as well as acute physical effects, and even months after the accident, hopelessness, depression, and post-traumatic stress can be seen in the child and the family (3). Child abuse can also underlie trauma. However, child abuse is considered only if the trauma is severe. Reports of abuse are very low, and children exposed to abuse experience varying degrees of physical, developmental, mental, and social retardation (5). These situations further increase the importance of evaluating childhood traumas.

Our aim in this study was to examine the pediatric trauma patients admitted to the emergency department and to determine the

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data such as age, gender, place of accident, trauma mechanism, examinations, and treatments, and to analyze whether there is any relation between these data.

Materials and Methods

Approval for this study was obtained from the İnönü University Health Sciences Scientific Research and Publication Ethics Committee with decision number: 2016/10-11, date: 02.08.2016. Our study was conducted by retrospectively analyzing the files of pediatric trauma cases in the 0-16 age group who applied to İnönü University Faculty of Medicine, Department of Emergency Medicine between January 01, 2013, and December 31, 2013, from the computer registry system. Six hundred nine pediatric trauma cases were included in the study; however, 36 patients were excluded because of archiving and recording system deficiencies. A total of 573 patients were reviewed. The exclusion criteria of the study were being 17 years of age or older and being younger than 17 years but admitted to the emergency department for a reason other than injury, and patients with injuries due to burns, suffocation, and animal bites.

Data Collection

A form was created with the title of evaluation of pediatric trauma patients, and the information of the patients who were screened using the hospital information management system was recorded in these forms. In addition to the information such as age and gender of the patients, monthly admissions, mechanism of trauma, the place where the trauma occurred, the consultations requested, the services where the patients were followed, the body parts exposed to the trauma, radiological and laboratory findings [hemoglobin (Hgb), hematocrit (Hct), mean corpuscular volume (MCV), platelets (PLT), white blood cells (WBC), red blood cell distribution width (RDW), creatine (Cr), blood urea nitrogen (BUN), aspartate aminotransferase (AST), alanine aminotransferase (ALT), glucose, activated partial thromboplastin time (aPTT), international normalized ratio (INR), haematuria, and leukocytes in urine] and the treatments given were specified. Then, the statistical relationships between them were examined. Patients were divided into four groups according to age groups: under one year, 1-5 years, 5-10 years, and over 10 years. Falls above 2 m height were grouped as falls from height, whereas falls from a distance below 2 m and impacts were grouped together. Crush and being stuck between two objects were grouped as crush injuries. Injuries that could not be included in other groups, such as object falls, were grouped as others. Treatments were divided into two groups: minor and major surgeries. Minor surgeries were grouped as operations performed under local anesthesia in emergency service conditions. Major surgeries were grouped as surgical interventions performed under operating room conditions.

Statistical Analysis

Quantitative data are summarized as median, minimum, and maximum, and qualitative data as number and percentage. The IBM Statistical Package for the Social Sciences statistics 25.0 program was used for statistical analysis. In analyzing the data for normality in quantitative data, the Kolmogorov-Smirnov test was used. Unpaired t-test and one-way analysis of variance were used in independent groups for normally distributed data, and Mann-Whitney U and Kruskal-Wallis tests were employed for data that did not show normal distribution. Multiple comparisons of the groups were performed using the Tukey test after a one-way analysis of variance and the Conover test following the Kruskal-Wallis test. The chi-square test was used in qualitative data to determine the difference between the groups. A p value of <0.05 was considered statistically significant.

Results

Of the 573 patients included in the study, 384 (67%) were boys and 189 (33%) were girls. The mean age of the patients was 6.44 ± 4.56 years. The mean ages of male and female pediatric patients were 6.90 ± 4.65 years and 5.52 ± 4.24 years, respectively. The distribution of patients by gender and age group is shown in Table 1. The most frequent admission was in patients aged between 1 and 5 years (41.5%), and the majority were male patients. When we looked at the age groups according to

Table 1. Distribution of patients by gender and age groups

Variable	Category	Statistics	Age group				Total
			0-1	1-5	5-10	>10	
Gender	Male	Number (n)	24	144	109	107	384
		Percentage (%)	4.2	25.1	19.0	18.7	67.0%
	Girl	Number (n)	14	94	51	30	189
		Percentage (%)	2.4	16.4	8.9	5.2	33.0%
Total		Number (n)	38	238	160	137	573
		Total (%)	6.6%	41.5	27.9	23.9	100.0

gender, a significant difference was found between the groups (p=0.006).

The number of admissions of children with trauma increased in July (12.2%), August (10.3%), September (10.1%), and October (10.65%). It was determined that the highest number of applications was in July, with 12.22%, but this was not statistically significant (p=0.380). Figure 1 shows the distribution of patients with trauma admissions by months.

In our study, it was determined that 333 (58.11%) patients were admitted to our clinic due to falls and hit from a distance below the height limit of 2 m, 22 (3.83%) fell from height, 25 (4.36%) were exposed to assault-abuse, 12 (2.09%) were in-vehicle collisions, 11 (1.91%) pedestrian injuries, 31 (5.41%) bicycle accident, 23 (4.01%) sports injury, 48 (8.37%) sharp-penetrating tool injuries, 45 (7.85%) crush injuries, and 23 (4.01%) with other injuries. Among the trauma mechanisms, falls and impacts were found to be the most common type of trauma, with a rate of 58.11%. When we looked at the trauma mechanisms by gender, no significant difference was found between the groups (p=0.084).

As the information on the site of trauma could not be accessed for 103 of the patients, it was determined that in 281 (59.8%) of the remaining 470 patients, trauma occurred at home, and home was the most common trauma place. The number and percentage of trauma areas are given in Table 2.

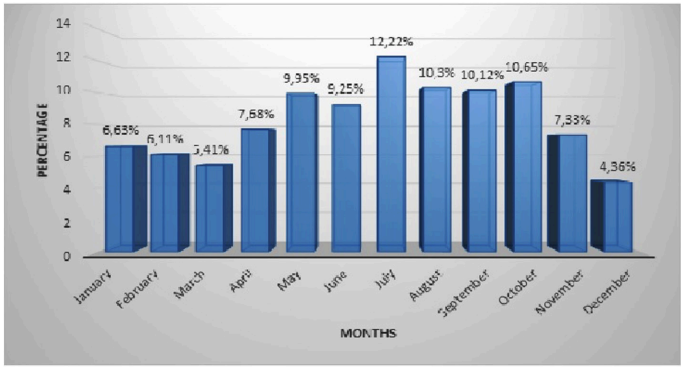

Figure 1. Diagram of the distribution of trauma patients admissions by months

Table 2. Number and percentage of trauma area		
Trauma place	**Number (n)**	**Percentage (%)**
Home	281	59.8
School	22	4.7
Playground	26	5.5
Hospital	4	0.9
Street/Road/Garden	124	26.4
Pool/Gymnasium/AstroTurf	13	2.8
Total	470	100.0

When the patients in our study were separated and evaluated by the areas exposed to trauma, it was found that head and neck injury was with 367 (64%), and extremity injuries were in the second place with 240 patients (41.9%). The number and percentage of areas exposed to trauma are given in Table 3.

In 422 (73.64%) patients, only one body region was affected because of trauma, and 166 (39.33%) completed their treatment without hospitalization or follow-up. There were 151 (26.35%) patients with multiple trauma, and 13 (8.6%) of these patients were treated without hospitalization or follow-up. Hospitalization and follow-up rates of patients with multiple traumas were higher than those of patients with only one affected area, which was also significant (p<0.001).

It was specified that 5 (0.87%) of the 573 patients included in the study were deceased. It was determined that these patients had fallen from a height (3 patients) and had pedestrian injuries (2 patients).

Of 573 cases admitted to the emergency department, 208 (36.30%) were treated by emergency physicians without asking for consultation. The most frequent consultations were requested from the orthopedics, traumatology, and neurosurgery departments.

Whole blood count in 163 (28.4%) patients, blood biochemistry in 152 (26.5%) patients, complete urinalysis in 39 (6.8%) patients, coagulation parameters in 16 (2.8%) patients, and blood group analyses in 59 (10.3%) patients were performed.

Direct radiography was requested most frequently as a radiological imaging method. Direct radiography was requested from 358 (62.47%) patients, and pathology secondary to trauma was found in 56 (15.6%) patients. After direct X-ray, computed tomography (CT) was the most preferred imaging method as the radiological imaging method in 190 (33.15%) patients, and pathology secondary to trauma was detected in 54 (28.4%) patients. Ultrasonography (USG) was requested from 104 (18.15%)

Table 3. Number and percentage of traumatized areas	
Injured body part	**n* (%)**
Head-neck	367 (64)
Thorax	127 (22.2)
Abdomen	150 (26.2)
Pelvis	76 (13.3)
Extremity	240 (41.9)
Vertebral column	72 (12.6)
Genital area	11 (1.9)
*Numbers are determined according to the presence of more than one body area injury in a patient	

patients, and pathology secondary to trauma was detected in 6 (5.76%) patients.

Treatments given to the patients were grouped as those who did not receive treatment, those who received medical treatment, those who underwent minor surgery, those who underwent major surgery, and those who underwent resuscitation. Treatments according to the trauma mechanism were determined. The total number of patients with crush injuries was 45, and major surgery was performed on 26 (57.7%) patients in an operating room environment, and minor surgery was performed on 9 (20%) patients in the emergency department. The number and percentage of treatments performed according to the trauma mechanism are given in Table 4.

Of the total patients, 214 (37.3%) patients admitted with fall impact were followed up in the emergency department. Of the patients with fall-impact injuries, only 1 case was admitted to the neurosurgery ward. Of the 45 cases with crush injuries, 33 were admitted to the emergency department, followed up, and treated. Of the 22 patients who fell from a height, 4 received outpatient treatment, 16 were hospitalized in the inpatient department of the emergency service, and one was hospitalized in the neurosurgery ward. Inpatient follow-up was recommended for a patient, but the patient's relatives did not accept hospitalization. According to the trauma mechanism, the number and percentage of hospitalizations and follow-ups are listed in Table 5.

The relationship between the injured area and laboratory parameters (Hgb, Hct, MCV, PLT, WBC, RDW, Cr, BUN, AST, ALT, glucose, aPTT, INR, haematuria and leukocyte in urine) and age were examined.

It was established that head and neck injuries increased as age decreased ($p<0.001$). Hgb and Hct values of patients with head and neck injuries were significantly lower than those without head and neck injuries ($p=0.016$, $p=0.043$, respectively). RDW, BUN, MCV, and AST values of patients with head and neck injuries were observed to be significantly higher than those without head and neck injuries ($p=0.025$, $p=0.016$, $p=0.014$, $p=0.046$, respectively). Table 6 shows the relationship between head and neck injury and laboratory parameters.

Hgb and Hct values of patients with thoracic injuries were lower than those of those without thoracic injuries ($p=0.012$, $p=0.035$, respectively).

When the relationship between abdominal injuries and parameters was reviewed, abdominal trauma increased as age decreased ($p=0.041$). Hgb and Hct values of patients with abdominal injuries were lower than those of those without abdominal injuries ($p=0.006$, $p=0.014$, respectively). AST and ALT values of patients with abdominal trauma were higher than those without abdominal trauma ($p=0.016$, $p=0.026$, respectively).

When the relationship between pelvic injury and parameters was examined, Hgb and Hct values were lower in patients with pelvic

Table 4. Number and percentage of treatments performed according to trauma mechanism

		Trauma mechanism										
Variable	Value	Fall-impact	Fall from height	Assault-abuse	In-vehicle collisions	Pedestrian Injuries	Bicycle accident	Sports injury	Sharp-penetrating tool injuries	Crush	Others	Total
Untreated patient	(n)	111	2	11	7	2	6	14	3	2	6	164
	(%)	19.4	0.3	1.9	1.2	0.3	1.0	2.4	0.5	0.3	1	28.6
Medical treatment	(n)	154	15	12	5	6	19	6	19	8	13	257
	(%)	26.9	2.6	2.1	0.9	1.0	3.3	1.0	3.3	1.4	2.3	44.9
Minor surgery	(n)	68	2	2	0	1	6	2	25	9	1	116
	(%)	11.9	0.3	0.3	0.0	0.2	1.0	0.3	4.4	1.6	0.2	20.2
Major surgery	(n)	0	0	0	0	0	0	1	1	26	3	31
	(%)	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.2	4.5	0.5	5.4
Resuscitation	(n)	0	3	0	0	2	0	0	0	0	0	5
	(%)	0.0	0.5	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	0.9
Total	(n)	333	22	25	12	11	31	23	48	45	23	573
	(%)	58.1	3.8	4.4	2.1	1.9	5.4	4.0	8.4	7.9	4.0	100.0

injury than in those without pelvic injury (p=0.001, p=0.002, respectively). AST and ALT values were higher in patients with pelvic injury (p<0.001, p=0.017, respectively).

No statistically significant relationship was established between genital injuries and other parameters.

Considering the relationship between vertebral injuries and parameters, Hgb and Hct values were lower in patients with vertebral injuries (p=0.001, p=0.003, respectively). AST and RDW values of patients with vertebral injury were higher than those without vertebral injury (p=0.000, p=0.046, respectively).

Table 5. The number and percentage of hospitalization and follow-up by trauma mechanism

		Trauma mechanism										
Variable	**Value**	**Fall-impact**	**Fall from height**	**Assault-abuse**	**In-vehicle collisions**	**Pedestrian injuries**	**Bicycle accident**	**Sports injury**	**Sharp-penetrating tool injuries**	**Crush**	**Others**	**Total**
Outpatient discharge	Number (n)	93	4	12	1	3	4	11	30	12	9	179
	Percentage (%)	16.2	0.7	2.1	0.2	0.5	0.7	1.9	5.2	2.1	1.6	31.2%
Follow-up was recommended in the emergency department, but not accepted	Number (n)	25	1	0	4	0	3	0	0	0	1	34
	Percentage (%)	4.4	0.2	0.0	0.7	0.0	0.5	0.0	0.0	0.0	0.2	5.9
Follow-up in the emergency department	Number (n)	214	16	12	7	8	22	11	16	33	13	352
	Percentage (%)	37.3	2.8	2.1	1.2	1.4	3.8	1.9	2.8	5.8	2.3	61.4%
Hospitalization in a ward other than emergency	Number (n)	1	1	1	0	0	2	1	2	0	0	8
	Percentage (%)	0.2	0.2	0.2	0.0	0.0	0.3	0.2	0.3	0.0	0.0	1.4
Total	Number (n)	333	22	25	12	11	31	23	48	45	23	573
	Percentage (%)	58.1%	3.8	4.4	2.1	1.9	5.4	4.0	8.4	7.9	4.0	100

Table 6. Relationship between head and neck injury and laboratory parameters

Variable	**No head-neck injuries**			**Head and neck injury present**			
	Median	**Minimum**	**Maximum**	**Median**	**Minimum**	**Maximum**	**p value**
Age (month)	81.5	7	202	58	1	199	**<0.001**
Hgb	13.1	11.3	15.7	12.6	2.9	16.3	**0.016**
Hct	38.30	32.10	45.60	37.50	8.60	47.30	**0.043**
MCV	83.10	70.50	91.40	81.00	39.10	98.20	**0.014**
PLT	304	181	509	297	14	556	0.735
WBC	10.40	5.00	17.40	10.40	2.70	33.70	0.592
RDW	13.55	11.80	17.70	14.10	12.50	27.50	0.025
Cr	0.57	0.43	0.74	0.54	0.40	6.3	0.278
BUN	12	7	20	11	4	27	**0.016**
AST	28.50	17	242	32	13	657	**0.046**
ALT	17.50	11	153	18	8	115	0.701
Glucose	100	75	220	102	70	378	0.995
aPTT	30.8	27.5	31.7	32.45	26.8	44.7	0.248
INR	1.05	1.0	1.1	1.05	1.0	2.0	0.789
Haematuria	1	0	19	1	0	5	0.939
Leukocyte in urine	1	0	8	1	0	6	0.183

Hgb: Hemoglobin, Hct: Hematocrit, MCV: Mean corpuscular volume, PLT: Platelets, WBC: White blood cells, RDW: Red blood cell distribution width, Cr: Creatine, BUN: Blood urea nitrogen, AST: Aspartate aminotransferase, ALT: Alanine aminotransferase, aPTT: Activated partial thromboplastin time, INR: International normalized ratio

When the relationship between extremity injuries and parameters was examined, it was found that extremity injury increased as the age increased (p=0.009). AST, ALT, and RDW values were higher in patients with extremity injuries (p=0.025, p=0.048, p=0.024, respectively).

Discussion

Our study determined that the number of admissions was higher in pediatric patients who were admitted to the emergency department with trauma between the ages of 1-5 and in boys. Child traumas were higher in July, August, September, and October than in other months. Falls and impacts were found to be the most common mechanism among the trauma etiologies of our patients. The most frequent traumas occurred at home. The mortality rate was determined to be 0.87%. When the areas exposed to trauma were examined, it was seen that head and neck injuries took the first place. The number of admissions of pediatric patients with isolated region injuries was higher than those with multiple traumas; however, hospitalization and follow-up rates of patients with multiple traumas were higher. The most frequently studied examination was complete blood count, and direct radiography was the preferred radiological imaging method. Consultation was most frequently requested from the orthopedics and traumatology department, and the second most frequent consultation was requested from the neurosurgery department. It was observed that most of the hospitalized patients were followed up in the emergency department. It was found that head-neck injuries increased significantly as age decreased. Hgb and Hct values of patients with head and neck injuries were significantly lower than those of patients without head and neck injuries, and MCV, RDW, BUN, and AST values were significantly higher. The Hgb and Hct values of patients with thoracic injuries were found to be significantly lower than those of those without thoracic injuries. The abdominal trauma of the patients increased as the age decreased, and the Hgb and Hct values of the patients with abdominal injuries were significantly lower than those without abdominal injuries, and the AST and ALT values were significantly higher. The Hgb and Hct values of patients with pelvic injury were significantly lower than those without, and the AST and ALT values were significantly higher. In patients with vertebral injury, Hgb and Hct values were significantly lower than those in patients without vertebral injury, and AST and RDW were significantly higher. Extremity injury significantly increased with age, and AST, ALT, and RDW were significantly higher in patients with extremity injury than in those without extremity injury.

In a study conducted, it was found that among pediatric patients admitted to the hospital due to trauma, the rate of male and female admissions was 65/35, and the mean age was 6.6±4.4 years (3). In another study, the male/female ratio was reported as 2.35/1, the mean age of the patients as 6.14, and the most common age group as 6-12 years (6). In another study, 61.1% of the pediatric trauma admissions were male and 37.2% were female (7). In another study analyzing child traumas, the ratio of males was 73%, whereas the ratio of females was 27%, and the most common age group was between 2 and 7 years old (8). In another study, it was reported that the ratio of males and females was 1.7, the mean age of males was 8.11±5.19, the mean age of females was 6.89±5.04, and the most common age of trauma was 7-14 (9). In our study, 384 (67%) of 573 patients were male and 189 (33%) were female, and the mean age of the patients was 6.44±4.56 years. The mean age of male and female pediatric patients was 6.90±4.65 years and 5.52±4.24 years, respectively. The most common admissions were between the age range of 1-5; most were male patients.

Paediatric trauma cases are mostly admitted to hospitals in spring and summer (9). Similarly, in our study, the number of admissions in July (12.2%), August (10.3%), September (10.1%), and October (10.65%) was higher than that in the other months. The highest number of admissions was found to be in July with a ratio of 12.22%, and when the distribution of age groups by month was analyzed, the number of admissions in July was higher for each age group compared with other months. Naturally, trauma-related admissions increase in the summer months. However, contrary to the literature, our study's number of applications is also high in September and October.

Falls were determined to be the leading cause of injury among patients who were admitted to emergency departments because of injury (10). Falls are one of the most common injury mechanisms in children (11-13). Because motor skills develop over time, fine motor movements, walking, and balance functions are not fully developed in children (14,15). Caution should be taken during falls, which are an essential cause of child injury and death. A seemingly minor fall can result in irreversible injuries (13). We also determined in our study that falls and impacts were the most common traumas, with a rate of 58.11%.

It was determined that among the places where pediatric injuries occurred, the home was with a rate of 60.8%, and the street was in the second place with a rate of 16.8% (6). In another study, it was found that pediatric accidents occurred most commonly at home with a rate of 52.3% and in the street with a rate of 19.3% (3). Our study also observed that child traumas occurred most commonly at home with a rate of 59.8%.

In a study that examined pediatric forensic cases under 16 years of age admitted to the emergency department, it was found that

the mortality rate was 0.4% (16). In another study examining pediatric trauma cases, the mortality rate was 0.11% (9). Another study determined the overall mortality rate in pediatric trauma as 0.5% (17). Our study found that the mortality rate was 0.87%, and there was no significant difference between the mortality rates by gender.

In a study on accident-related injuries in children, it was stated that among the affected different body parts, extremities were 52.7%, head/face was 32.7%, spine was 7%, and multiple system injuries were 14.6% (3). In another study, extremity injury was found to be with a rate of 55.5%, and head-neck injury was in the second place with a rate of 47.5% (6). When the patients' body parts exposed to trauma were examined in our study, we found that head-neck injuries were with a rate of 64%, and extremity injuries were in the second place with a rate of 41.9%.

In our study, it was observed that only one body part was affected by the trauma, with a rate of 73.64%, and 39.33% of these patients' treatments were completed without hospitalization and follow-up. The rate of patients with multiple traumas was 26.35%. Hospitalization and follow-up rates of patients with multiple traumas were significantly higher than those of patients with only one affected body part.

In our study, among the blood tests requested from the patients were whole blood count with a rate of 28.4%, biochemistry at 26.5%, coagulation parameters at 2.8%, and blood group tests at 10.3%. Additionally, a complete urinalysis was performed at a rate of 6.8%. In a study that examined pediatric traumas, direct radiography was performed at a rate of 57.3%, CT at a rate of 37.8%, and USG at a rate of 2.1% (18). In another study, the most commonly requested examination from patients was direct X-ray with a rate of 53.7%, followed by brain CT with a rate of 21.3%, and abdominal USG with a rate of 2.6% (6). In a study conducted with 697 patients (89.6%), only direct radiography was requested, whereas 27 (3.6%) required both direct radiography and CT (19). Direct radiographs were performed at a rate of 62.47%, CT at a rate of 33.15%, and USG at a rate of 18.15% as radiological imaging methods in the patients included in our study.

In a study, consultation was mainly requested from the orthopedics department at a rate of 39%, followed by the neurosurgery department at a rate of 28.8% for pediatric trauma cases (6). In our study, consultation was mostly requested from the orthopedics department with a rate of 22.16% and then from the neurosurgery department with a rate of 21.11%, and 36.3% of our patients' consultations were not requested from any department.

The hospitalization rate of pediatric trauma patients was determined to be 4.3% (9). In our study, the rate of patients who were admitted to a ward other than the emergency department was 1.4%. In our study, the low rate of inpatient follow-up can be explained by having an inpatient department in our emergency department and following up on trauma patients in this department.

In our study, head-neck injuries were determined to increase significantly as age decreased, depending on age. The head-to-body ratio of the pediatric age group was larger than that of adults. A bigger head causes the center of gravity to be higher than that of adults; therefore, head trauma is one of the most common childhood injuries.

It has been reported that RDW predicts mortality in trauma patients independently (20). It has also been shown that there is a relationship between high RDW and mortality in traumatic brain injuries (21). In another study conducted with trauma patients, RDW values were higher, and MCV and Hgb values were lower in patients with chest, extremity, and head trauma than in controls (22). In a study conducted on children younger than 2 years with severe head trauma, Hgb and Hct values were significantly lower in deceased cases than in survivors (23). It has been reported that patients with severe head trauma can have high BUN values at admission (24). However, studies have demonstrated that no routine blood test measured at admission can significantly predict outcomes in patients with severe traumatic brain injury (25). Our study found that patients with head and neck injuries had significantly lower Hgb and Hct values and significantly higher MCV, RDW, BUN, and AST values than those without head and neck injuries. Additionally, our study determined that extremity injuries increased significantly with age, and AST, ALT, and RDW were significantly higher in patients with extremity injuries. In our study, Hgb and Hct values were significantly lower in patients with thoracic injuries than in those without thoracic injuries.

Because they have less subcutaneous fat, larger heads, and larger abdominal solid organs than adults, severe and multiple injuries are common in pediatric high-energy trauma patients (26). In pediatric abdominal trauma patients, acute anemia and high AST and ALT values are important in terms of showing the severity of the trauma and being a warning in terms of tomography (27). A study stated that in pediatric pelvis fractures, the mean decrease in Hgb levels was 1.5 g/dL (28), although severe bleeding is rarer in pediatric patients than in adults. Hgb and Hct values of patients with abdominal injury were significantly lower, and AST and ALT values were significantly higher than those of patients without abdominal injury. Our study found that abdominal trauma of the patients increased as age decreased. Hgb and Hct values of patients with abdominal injury were significantly lower, and AST

and ALT values were significantly higher than those of patients without abdominal injury. Hgb and Hct values were significantly lower, and AST and ALT values were significantly higher in patients with pelvic injury.

A study found that high RDW was associated with an increased probability of vertebral fracture in the elderly (29). It was determined that Hgb and Hct values were significantly lower and AST and RDW were significantly higher in patients with vertebral injuries in our study.

Having adequate knowledge about trauma patients' demographic and trauma-related characteristics will ensure that the treatments are faster and more effective. As accidents are preventable, in addition to health workers, non-health workers should also be informed about the results of such studies and provided with adequate training. We believe that multicenter studies conducted with more patients will provide us with more precise information on this subject, and additionally, it will be appropriate for countries to establish government policies on the subject to reduce accidents.

Study Limitations

The limitations of our study can be noted as being single-center, number of cases, a 1-year cross-sectional period, and being retrospective.

Conclusion

Because of our study, it has been determined that in terms of the incidence of pediatric traumas, there were different etiological causes and trauma areas, and their frequency varied seasonally. The injured body area mainly was the head-neck region. Head-neck and abdominal injuries increased as age decreased, extremity injuries increased as age increased, and in pediatric traumas, a good evaluation of the blood tests was critical in the assessment and follow-up of patients and to avoid missing some injuries.

Ethics

Ethics Committee Approval: Approval for this study was obtained from the İnönü University Health Sciences Scientific Research and Publication Ethics Committee with decision number: 2016/10-11, date: 02.08.2016.

Informed Consent: Retrospective study.

Authorship Contributions

Concept: E.Y., M.G.T., C.Ç., Design: E.Y., M.G.T., C.Ç., Data Collection or Processing: E.Y., M.G.T., C.Ç., Analysis or Interpretation: C.Ç., Literature Search: E.Y., M.G.T., Writing: E.Y., M.G.T.

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Efficacy of Intravenous Paracetamol, Dexketoprofen, and Ibuprofen in Treating Headache Induced by Acute Migraine Attack

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Abstract

Aim: Migraine is the most prevalent cause of admission to the emergency department (ED) with pain complaints. This study seeks to provide a comparative evaluation of the efficacy of intravenous paracetamol, dexketoprofen, and ibuprofen in treating headache induced by acute migraine attack.

Materials and Methods: Two hundred and seven volunteers with headache due to migraine attack were randomized into three groups. Group I was administered with intravenous paracetamol, Group II with intravenous dexketoprofen trometamol, and Group III with intravenous ibuprofen. A 100-mm visual analogue scale (VAS) score was used as an assessment scale to monitor dynamic changes in headaches during the 1-h observation of migraineurs.

Results: In Group I, the mean baseline VAS score was 79.65±13.87 and 11.83±14.37 at 60 min. In Group II, the mean baseline VAS score was 77.14±11.31 and 7.79±14.37 at 60 min. In Group III, the mean VAS score decreased from baseline 76.89±11.92 to 6.67±10.13 after 60 min. Considering the ΔVAS scores 30-min scores differed significantly between Group I and Group III (p=0.009).

Conclusion: IV paracetamol, dexketoprofen, and ibuprofen treatments did not differ significantly in acute migraine therapy. IV ibuprofen may be a first-line choice in EDs because of its immediate analgesic effect.

Keywords: Dexketoprofen, emergency department, ibuprofen, migraine, acetaminophen

Introduction

A large portion of the admissions to the emergency department (ED) with headache complaints are due to acute migraine attacks. The prevalence of migraine, one of the most common neurological disorders, is estimated to be around 15% in a one-year period across the world. Particularly in southeast Asia, the one-year prevalence reaches 25-30% (1). Recent research sets the prevalence of migraine at 11.7% in the USA, and gender-wise analysis reveals that its prevalence was 17.1% in females and 5.6% in males (2). In the Turkish context, its incidence was established as 2.38% (3), and its lifetime prevalence was 19.9% in men and 29.3% in women (4).

The treatment of headache induced by acute migraine attack in the ED is aimed at producing rapid, effective, and reliable analgesia with the least undesirable side effects, which does not trigger migraine and avoids the recurrence of pain after discharge. Although narcotic analgesics are likely to provide potent therapeutic effects and rapid onset of action, they can nevertheless present side effects, such as hypotension, nausea, vomiting, and dizziness (5). Therefore, paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs), such as dexketoprofen and ibuprofen, are frequently administered in the treatment of acute headache associated with migraine attack in EDs (5). Compared with NSAIDs, acetaminophen offers a wide margin of safety and a low incidence of side effects (6). The effectiveness of

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acetaminophen in migraine headaches and its potential to be an alternative to other analgesics are crucial research topics that warrant further clinical investigation. Comparative studies are required to remove the question mark over which drug should be preferred (7).

Within this context, the present study seeks to provide a comparative evaluation of the efficacy of intravenous paracetamol, dexketoprofen, and ibuprofen in treating headache induced by acute migraine attack.

Materials and Methods

Study Design and Subjects

Our study was conducted at Pamukkale University Hospital Emergency Service between June 2018 and February 2020. This clinical trial was approved by the Pamukkale University Non-Interventional Clinical Research Ethics Committee (date: 29.05.2018, number: 11) and subsidized by the Pamukkale University Coordination Unit of Scientific Research Projects (2019TIPF006). Our study was registered and approved by the American clinical trial registry (NCT04372264 at https://clinicaltrials.gov). Our ED accomdates 120,000 annual patient encounters and during the study period a research assistant and/or faculty member managed this research 24 hours per day.

Among the patients admitted to the ED with the complaint of headache, those who met the 'International Classification of Headache Disorders' criteria for migraine without aura (8) and agreed to participate were recruited for our study after being evaluated in accordance with the inclusion and exclusion criteria.

Group I: Intravenous paracetamol (1000 mg) (Parol 1000 mg vial – Atabay Chemistry – İstanbul)

Group II: Intravenous Dexketoprofen Trometamol (50 mg) (Arveles 50 mg ampoule – Menarini – İstanbul)

Group III: Intravenous ibuprofen (400 mg) (Intrafen 400 mg vial – Gen – İstanbul)

After randomization, the drugs were diluted in 150 mL of physiological saline at the above-mentioned doses and administered as intravenous infusion (15 min). In addition, 10 mg metoclopramide in 150 cc physiological saline was administered intravenously to those with complaints of nausea as a 15-min slow infusion, concomitantly with the study drugs as standard care. Pain scores were assessed using the visual analog scale (VAS) at 0, 15, 30, and 60 min, and migraineurs were followed up in terms of vital signs and potential adverse effects. Each VAS score was marked on different forms. The migraineurs were followed up for 60 min in terms of efficacy, bioavailability, and complications of the drugs used in the study. The study was planned to terminate at 60 min, and patients with persisting pain were administered with a slow intravenous infusion of fentanyl 1 mcg/kg.

Data Collection

Our clinical trial recruited patients between the ages of 18 and 65 who presented to the ED with headache caused by acute migraine attack without aura, agreed to participate in the study, gave their informed consent, and matched the inclusion criteria. The specific considerations for patient selection are detailed in the following inclusion and exclusion criterion sections.

Inclusion Criteria:

- Suffering from headache due to acute migraine attack without aura,

- Being aged between 18-65,

- Providing written consent to participate in the study.

Exclusion Criteria:

- Taking analgesic drugs in the last 6 h,

- Taking ergotamine-derived drugs in the last 24 h,

- Being pregnant and during the lactation period,

- Being allergic to the study drugs,

- Hemodynamically unstable,

- Undergoing renal transplantation,

- Suffering from hepatic, renal, cardiac, and pulmonary insufficiency,

- Being a hypertensive patient whose blood pressure is not under control,

- A history of cerebrovascular disease,

- A history of ischemic heart disease or coronary spasm/prinzmetal angina,

- Having Wolff-Parkinson-White syndrome or arrhythmias accompanying accessory pathways,

- Suffering glucose 6 phosphate dehydrogenase (G6PD) deficiency,

- Having other systemic diseases,

- Having a VAS pain score of less than 50 mm,

- Illiterate and visually impaired,

- Patients with pathology on neurologic examination.

The study was planned to terminate in the event of any drug-related adverse effects observed during the study.

The relevant information of the eligible patients were noted in the study data form. A 100-mm VAS scale was used as the evaluation scale to track the dynamic changes in migraineurs' headaches. VAS markings in the evaluation form prepared for the study before and during the procedure were performed by the migraineurs themselves, regardless of the previous marking. The scores for acute migraine headache without aura were evaluated and recorded at 0, 15, 30, and 60 minutes.

Statistical Analysis

A power analysis was performed before the study, assuming that the difference between the study groups would have a small effect size (dz=0.3). Accordingly, when 59 participants were included in the study, 90% power would be achieved at 95% confidence interval. Thus, this study assigned 71 participants to the paracetamol group, 70 to the dexketoprofen group, and 66 to the ibuprofen group. A total of 207 migraineurs completed the study, and 95% power for VAS results was achieved for all three drugs at 95% confidence interval.

All statistical data were analyzed using Statistical Package for the Social Sciences v.22 package program. The continuous variables (age, pulse, respiratory rate, fever, VAS score, systolic and diastolic blood pressure) were presented as mean±standard deviation, whereas the categorical variables (gender, medication used, presence of nausea and rescue medication use) were presented as numbers and percentages. The conformity of the variables to the normal distribution was analyzed using visual (histogram and probability graphs) and analytical methods (Kolmogorov-Smirnov, Shapiro-Wilk tests). In the case of normal distribution, an independent sample t-test was performed to evaluate the difference between categorical binary variables. Moreover, when the parametric test assumptions were met, the difference between categorical triple variables was analyzed using independent ANOVA. The categorical variables were compared using the chi-square test. The cases where the p value was below 0.05 were considered statistically significant.

Results

Of 207 migraineurs investigated within the scope of our study, 164 (79.2%) were women and 43 (20.8%) were men (Figure 1), with a mean age of 32.8 years. The medications used for migraine treatment included paracetamol given to 71 (34.3%) patients in Group I, dexketoprofen trometamol provided to 70 (33.8%) patients in Group II, and ibuprofen administered to 66 (31.9%) patients in Group III. Metoclopramide, on the other hand, was administered concomitantly to 158 (76.3%) migraineurs with nausea. Rescue therapy was performed for 6 (2.9%) migraineurs whose VAS scores were not reduced to below 50 mm. Four migraineurs in Group I required rescue therapy, whereas Groups II and III included one migraineur each who required this therapy. However, no significant difference was observed in the administration of rescue therapy between the three groups (p=0.238). Similarly, no significant difference was evident between the study groups with respect to gender, presence of nausea, and administration of rescue therapy (Table 1). No migraineurs in the study groups reported any side effects.

Clinical evaluation revealed a mean heart rate 81 beats per minute, respiratory rate 14 breaths per minute, and temperature of 36.8 °C with no significant difference noted between the groups in vital signs at baseline or any time point in the first hour after drug administration.

When the VAS scores were analyzed comparisons between groups yielded no significant difference in relation to baseline VAS scores. Also all three drugs were evaluated within themselves, a significant decrease was revealed at 15, 30, and 60 mins in comparison to the baseline score (Figure 2). The 15-min VAS score was 58.15±16.60 in the paracetamol group (I), 53.57±14.65 in the dexketoprofen trometamol group (II) and 50.61±16.16 in

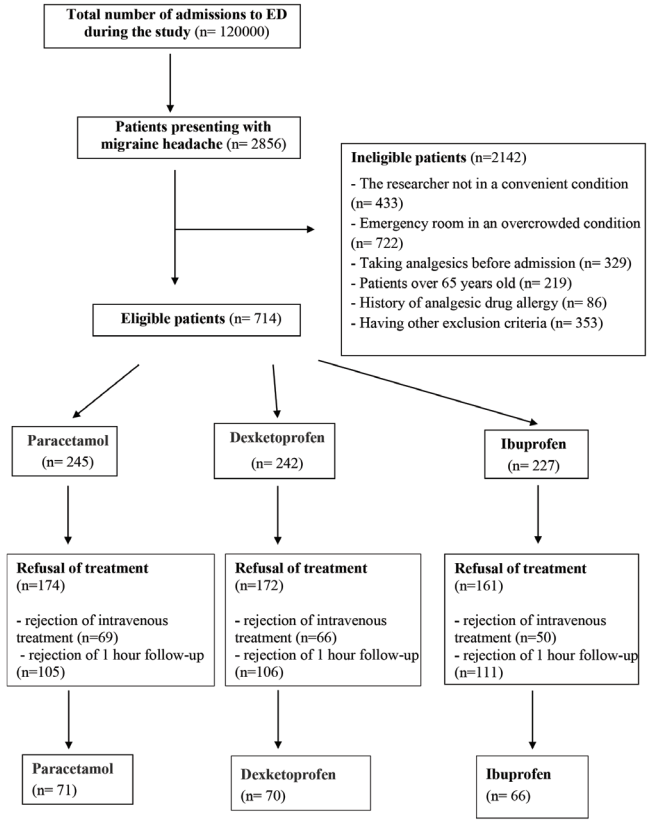

Figure 1. Flow chart
ED: Emergency department

Table 1. Demographic characteristics of the migraineurs and the study drugs					
	n (%)	**Group I paracetamol (n=71)**	**Group II dexketoprofen trometamol (n=70)**	**Group III ibuprofen (n=66)**	**p**
Gender	Female	60 (84.5%)	54 (77.1%)	50 (75.8%)	0.393
	Male	11 (15.5%)	16 (22.9%)	16 (24.2%)	
Presence of nausea	Yes	50 (70.4%)	58 (82.9%)	50 (75.8%)	0.219
	No	21 (29.6%)	12 (17.1%)	16 (24.2%)	
Rescue therapy	Yes	4 (5.6%)	1 (1.4%)	1 (1.5%)	0.238
	No	67 (94.4%)	69 (98.6%)	65 (98.5%)	
*Gender and presence of nausea presented as n (%). Pearson chi-square test was used. Significant values were highlighted in bold					

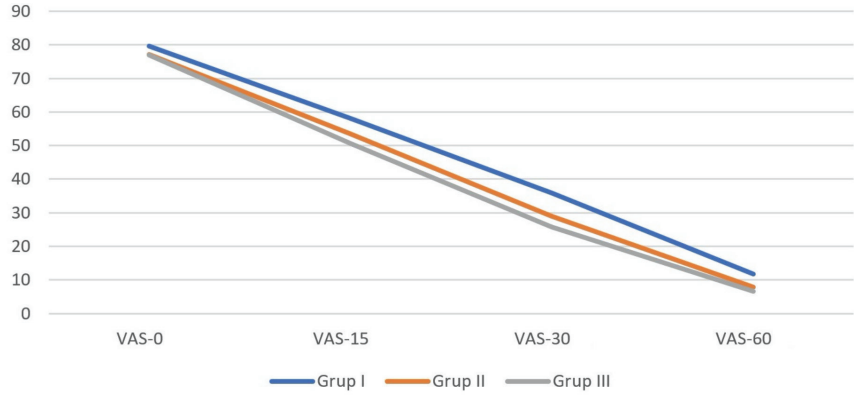

Figure 2. Time-dependent VAS score changes of the groups
VAS: Visual analogue score

the ibuprofen group (III). The 30-min VAS score was 35.92±17.69 in the Group (I), 28.93±16.13 in the dexketoprofen trometamol group II and 25.76±13.71 in the Group III. The 15- and 30-min VAS scores indicated significant differences between Group I and Group II, and between Group I and Group III (p=0.020) (p=0.001). Furthermore, statistical significance was noted between Group I, Group II, and Group III in the 60-min VAS scores (p=0.040). The ΔVAS 30-min score was 43.73±15.06 in the Group I, 48.21±13.88 in the Group II and 51.14±13.30 in the Group III. Considering the ΔVAS scores, 15- and 60-min VAS scores did not manifest a significant change between the groups (p>0.050), whereas 30-min scores differed significantly between Groups I, Group II and Group III (p=0.009) (Table 2).

No significant difference was detected between the patients in Group I and Group III given and not given metoclopramide concomitantly with the study drugs in terms of baseline, 15, 30, 60 min VAS, and ΔVAS scores (p>0.050). In Group II, no remarkable difference was found with respect to the baseline VAS, 30-min VAS, and ΔVAS scores between the migraineurs who were administered and not administered metoclopramide concomitantly with the study drug (p>0.050). The 15- and 60-min VAS scores of those not provided with metoclopramide were significantly lower (p=0.024; p=0.045). There was no significant change between 15- and 60-min ΔVAS scores (p>0.05) (Table 3). However, nausea symptoms were observed to disappear in all metoclopramide-given groups, and no add-on therapy was required.

Discussion

Our clinical trial on patients presenting with migraine-related acute headache without aura suggested that paracetamol, dexketoprofen, and ibuprofen significantly reduced VAS scores. The between-group analysis revealed that these drugs decreased VAS scores and produced an analgesic effect at a similar rate. Accordingly, IV forms of the aforementioned drugs administered to manage acute headaches can be an effective and safe treatment method. In addition, combined treatment with metoclopramide proved beneficial for treating nausea and vomiting accompanying migraine attacks.

In pain management, the migraineur should receive treatment as quickly as possible. Considering the treatment of migraine, the

Table 2. Distribution of the migraineurs' VAS scores across the groups

	Group I paracetamol (n=71)	Group II dexketoprofen trometamol (n=70)	Group III ibuprofen (n=66)	p
VAS 0 min	79.65±13.87	77.14±11.31	76.89±11.92	0.353
VAS 15 min	58.15±16.60	53.57±14.65	50.61±16.16	**0.020**
VAS 30 min	35.92±17.69	28.93±16.13	25.76±13.71	**0.001**
VAS 60 min	11.83±14.37	7.79±12.56	6.67±10.13	**0.040**
ΔVAS 15. min - 0 min	21.49±13.14	23.57±11.04	26.29±13.22	0.082
ΔVAS 30. min - 0 min	43.73±15.06	48.21±13.88	51.14±13.30	**0.009**
ΔVAS 60. min - 0 min	67.82±14.80	69.36±12.27	70.23±11.81	0.549

#VAS taken as mean±SD.
Differences were analyzed by ANOVA test.
Significant values were highlighted in bold. Absolute values were taken in ΔVAS scores.
SD: Standard deviation, VAS: Visual analogue scale

Table 3. Distribution of VAS scores of the patients in Group I (paracetamol + metoclopramide), Group II (dexketoprofen trometamol + metoclopramide), and Group III (ibuprofen + metoclopramide)

	Group I		p	Group II		p	Group III		p
	Paracetamol + metoclopramide (n=50)	Paracetamol only (n=21)		Dexketoprofen trometamol + metoclopramide (n=58)	Dexketoprofen trometamol only (n=12)		Ibuprofen + metoclopramide (n=50)	Ibuprofen only (n=16)	
VAS 0 min	80.90±13.65	76.67±14.26	0.243	78.28±11.10	71.67±11.15	0.065	77.30±12.30	75.63±10.94	0.628
VAS 15 min	58.78±17.94	56.64±13.17	0.628	55.34±14.17	45.0±14.46	**0.024**	51.60±17.65	47.50±10.0	0.381
VAS 30 min	37.60±18.80	31.90±14.36	0.218	30.09±15.91	23.33±16.70	0.069	26.40±14.68	23.75±10.25	0.505
VAS 60 min	13.0±15.56	9.05±10.91	0.294	8.71±13.20	3.33±7.79	**0.045**	7.20±11.07	5.0±6.33	0.328
ΔVAS 15 - 0 min	22.12±14.29	20.0±10.0	0.539	22.93±11.24	26.67±9.85	0.289	25.70±13.44	28.13±12.76	0.527
ΔVAS 30 - 0 min	43.30±15.21	44.76±15.04	0.712	48.19±13.60	48.33±15.86	0.974	43.30±15.21	44.76±15.04	0.712
ΔVAS 60 - 0 min	67.90±14.11	67.61±16.70	0.942	69.57±12.85	68.33±9.37	0.753	67.90±14.11	67.62±14.70	0.947

*VAS taken as mean±SD.
p obtained from the independent samples t-test.
Significant values were highlighted in bold.
SD: Standard deviation, VAS: Visual analogue scale

mean VAS score in the ibuprofen group was significantly lower than that in the paracetamol and dexketoprofen groups at 15 and 30 min and lower than that in the acetaminophen group at 60 min. Given the ΔVAS scores of all groups, ibuprofen was observed to provide a greater analgesic effect than acetaminophen at 30 min, although all drugs induced a similar decrease in the VAS scores at 60 min. These findings thus suggest that the analgesic effect of ibuprofen provides faster onset of action than other drugs. In parallel with our findings regarding ibuprofen, a recent comprehensive review established ibuprofen to be an effective and safe treatment for acute migraine headaches and a good option for the treatment of severe headaches because it produces relatively few side effects (9).

Turkcuer et al. (10) compared the effectiveness of IV paracetamol and dexketoprofen in acute migraine attacks, reporting that IV forms of these drugs achieved similar efficacy in pain control. Numerous clinical investigations have compared the administration of dexketoprofen trometamol alone or in combination with triptans with placebo and other analgesics, reporting that its administration alone or in combination proved effective in relieving migraine headaches (11-14).

Şafak et al. (15) compared the efficacy and safety of IV ibuprofen with IV dexketoprofen trometamol in 160 patients with migraine attack-related headaches. It was reported that a statistically significant difference was found in the VAS values at 30 min, and ibuprofen was more effective at the 30-min outcome, but no difference was found for the 60-min VAS values. Similar to this study, we found that VAS values were lower in the ibuprofen group than in the dexketoprofen trometamol group at 30 min, and ibuprofen was a faster agent. Contrary to the results of our study, Karacabey et al. (12) stated that pain relief with IV dexketoprofen was significantly higher and faster than that with ibuprofen.

An updated review study on the effectiveness and tolerability of acetaminophen alone or in combination with an antiemetic concluded that clinicians could resort to both applications to treat acute migraine attacks (16). In our study, there was no significant difference between the paracetamol group and the combination of acetaminophen and metoclopramide group in terms of VAS and ΔVAS scores and we thought that there is no superiority of the combination therapy of paracetamol with metoclopramide over acetaminophen alone.

Moore et al. (17) investigated the comparative efficacy of ibuprofen and paracetamol in migraineurs admitted to the ED with migraine headaches and documented the clinical superiority of ibuprofen across many acute and chronic pain conditions. Our study was found that ibuprofen had better VAS scores and acted faster at 30 min outcome when it compared to paracetamol.

Another aspect-deserving attention is that women experience migraine attacks three times more often than men (18,19). The incidence of migraine tends to increase in the female population along with the onset of puberty, and its prevalence among women of childbearing age far exceeds 15% (20). Although the reason for the gender-wise differences in migraine prevalence is not well established, some lines of evidence attribute this condition to lower pain resistance in women (21). Our study established that the proportion of female migraineurs was almost 80%, which broadly supports the work of other relevant studies.

The prevalence of migraine increases with age and shows a downward trend after the age of 40 years,with the mean age of patients at hospital admissions ranging between 35 and 40 years (22-24). As far as our results are concerned, the migraineurs were aged between 18 and 65 years,with the median value being 30 years and the mean age being 32.8 years, which is slightly lower than that reported in the literature. This situation might be because the ED of our tertiary hospital is located in a neighborhood where the inhabitants are predominantly young.

There is a growing academic interest in exploring the efficacy of metoclopramide in the treatment of acute migraine headaches. The mainstream view is that the co-administration of metoclopramide with existing drugs results in an efficacious treatment (25-27). In contrast to this view, other lines of evidence argue that metoclopramide does not achieve any clinical superiority over other treatments (28-30).

Metoclopramide is shown to produce a more potent analgesic effect at 15 min than ibuprofen and dexketoprofen, while ibuprofen proves less effective than dexketoprofen and metoclopramide (12). Dexketoprofen has also been shown to accelerate the pace of discharge of migraineurs from the ED (12). In a randomized double-blind controlled trial, Yavuz et al. (31) compared the effectiveness of IV metoclopramide versus dexketoprofen trometamol versus the combination of metoclopramide and dexketoprofen trometamol in a population of 150 patients. It was mentioned that no significant difference was found between the three treatment groups at the 15th min in terms of mean VAS scores, but the combination of metoclopramide and dexketoprofen trometamol was superior to both metoclopramide and dexketoprofen trometamol at the 30th min. Combination therapy was suggested for acute migraine pain in the ED. Similar to this study, a systematic review stated that the combination of metoclopramide and dexketoprofen gave better results than monotherapies in patients with migraine (32). Although we did not use metoclopramide for the treatment of migraine pain, contrary to the studies in existing literature, the combination therapy of dexketoprofen trometamol and metoclopramide had worse VAS scores than only dexketoprofen trometamol therapy in our study.

In our study, ibuprofen provided a faster onset of action than acetaminophen and dexketoprofen but exerted a similar effect at 60 min. The co-administration of the study drugs with metoclopramide did not contribute to any analgesic efficacy, except for the treatment of nausea and vomiting.

A systematic review probing the administration of ibuprofen alone and in combination with an antiemetic revealed that antiemetics showed minimal efficacy for treating migraine. However, the co-administration of ibuprofen with an antiemetic such as metoclopramide was observed to potentially provide better symptomatic relief from nausea and vomiting. It was also reported that ibuprofen could improve headache relief (33).

A randomized, double-blind, dose-ranging trial compared ibuprofen with both placebo and antiemetics on a population of 729 migraines. Given the clinical outcomes of the participants, ibuprofen reportedly reduced headache in about half of the patients and could be administered safely at a range of doses (34). In another double-blind, randomized and placebo controlled study, it was demonstrated that more pain relief within 2 hours after intravenous ibuprofen than placebo infusion (35).

Study Limitations

The results of the present study may have been affected by some limitations, including the absence of a comparison of the study drugs with placebo, inadequate follow-up period in terms of mobilization and functional capacity, and not assessing the recurrence of pain, re-admissions, and duration of ED stay. Another limitation can be cited as the exclusion of the migraineur using analgesics in the last six hours or an ergotamine-derivated

medication in the last 24 hours. The 60-min time span of the study might also be considered short.

Conclusion

Treatments performed with IV paracetamol, dexketoprofen, and ibuprofen generate similar analgesic effects, and these drugs can be considered safe for treating acute migraine without aura. Metoclopramide can be co-administered with the above-mentioned drugs in migraine therapy to prevent nausea. Because of its immediate analgesic effect, ibuprofen may be a first-line choice for treating headaches caused by acute migraine attacks in EDs.

Ethics

Ethics Committee Approval: This study was approved by the Pamukkale University Non-Interventional Clinical Research Ethics Committee (date: 29.05.2018, number: 11).

Informed Consent: Consent form was filled out by all participants.

Authorship Contributions

Surgical and Medical Practices: Ş.Ö., A.O., İ.T., Concept: Ş.Ö., A.Y., İ.T., Design: Ş.Ö., A.Y., İ.T., Data Collection or Processing: Ş.Ö., A.O., A.K., M.U., Y.K.Ç., E.D., M.S., M.Ö., İ.T., Analysis or Interpretation: Ş.Ö., A.Y., A.K., M.U., Y.K.Ç., İ.T., Literature Search: Ş.Ö., A.Y., A.O., A.K., M.U., E.D., M.S., M.Ö., İ.T., Writing: Ş.Ö., A.Y., A.O., A.K., M.U., Y.K.Ç., İ.T.

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Utilization of Nitinol Shape Memory Plates in the Surgical Treatment of Displaced Clavicle Fractures

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Abstract

Aim: While conservative and surgical options exist for treating displaced clavicle fractures, surgical intervention is often necessary, particularly in cases of comminuted fractures. This study aimed to assess the outcomes of surgical treatment using nitinol plates for displaced clavicle fractures.

Materials and Methods: A retrospective analysis was conducted on 19 patients with displaced midshaft clavicle fractures who underwent surgery with shape memory nitinol plates for clavicle fixation, all performed by the same surgeon. Data collection spanned a 7-year period from 2014 to 2021. Radiological and clinical assessments were conducted at a minimum 1-year follow-up.

Results: Nineteen patients (19 males), with a median age of 40.4 (range: 18-67) years, were included in the study. No major complications were observed during follow-up. Results indicated that 18 of 19 patients (94.7%) had fully recovered clinically and radiologically at the 1-year follow-up.

Conclusion: The use of nitinol plates in the surgical treatment of displaced clavicle fractures demonstrated successful outcomes. We believe that it can be safely preferred in selected cases because of its low complication rate.

Keywords: Displaced clavicle fracture, clavicle fracture fixation, shape memory nitinol plate

Introduction

The occurrence of a clavicle fracture indicates severe trauma, with clavicle fractures constituting 4% of all fractures and 35% of fractures in the shoulder region (1). The clavicle is anatomically divided into the medial, midshaft, and lateral regions (2). The midshaft, which constitutes the narrowest part of the clavicle, is the most commonly affected region, with approximately 80% of fractures occurring in this region. Various materials, including plaques and intramedullary implants, are available for surgical treatment, with a preference for surgical intervention and nitinol plates, especially for midshaft fractures (3). Nitinol alloy plates, which are characterized by high biocompatibility and minimal tissue reaction, are promising biomaterials (4). This study evaluated the outcomes of surgical treatments for displaced clavicle fractures using nitinol plates at our clinic.

Materials and Methods

This retrospective study involved the review of medical records from 29 patients with clavicle fractures who presented to the emergency department. Excluding four patients requiring intensive care unit follow-up and six patients with multiple traumas, we analyzed records from 19 patients with displaced midshaft clavicle fractures who underwent surgery using shape memory nitinol plates for clavicle fixation, all performed by the same surgeon. Data spanning a 7-year period (2014-2021) were collected, and radiological and clinical outcomes were evaluated with a minimum 1-year follow-up. The study was approved by the University of Health Sciences Turkey, Medeniyet University, Göztepe Training and Research Hospital Ethics Committee (decision no: 2023/0603, date: 20.09.2023).

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Statistical Analysis

Statistical analysis was conducted using Statistical Package for the Social Sciences (SPSS) 17.0 (IBM Inc Relased 2008). SPSS Statistics for Windows Chicago, USA) program. In descriptive statistics, continuous variables are expressed as mean±standard deviation, and categorical variables are expressed as percentages.

Surgical Technique

Patients were positioned supine under general anesthesia with antibiotic prophylaxis and underwent oropharyngeal intubation with a single lumen tube. The fractured arm was positioned parallel to the body, and the shoulder was elevated with support under the scapula. The position was adjusted accordingly. An incision line was marked on the clavicle to stabilize the fracture, and the surgical field was prepared using Betadine solution. With a 5-6 cm incision parallel to the clavicle, minimal dissection was performed to deperiostealize the clavicle, the fractured bone ends were aligned, and the nitinol plates, thawed with frozen physiological serum and opened with special clamps, were placed on the clavicle. Sterile physiological serum heated to +45-50 °C was diffused onto the plate delays, causing the plate delays to curve and grasp the clavicle, stabilizing the fracture site. Following anatomical closure of the subcutaneous tissues and skin, the operation was concluded. No complications were observed, and none of the patients required intensive care or postoperative mechanical ventilation. Pain control was achieved through acetaminophen and tramadol injections. Postoperative motor and sensory examinations of the upper extremities were normal (Figures 1, 2).

Results

All patients in this study were male, with ages ranging from 18 to 67 (mean: 40.4). All fractures were displaced and located in the middle third of the clavicle. Nitinol plates were used in the surgical treatment of all patients. Four cases (21%) presented with rib fractures, and one case (10.5%) had a scapula fracture accompanying the clavicle fracture. Clavicle fractures were identified on the right side in 10 patients (52.6%) and on the left side in 9 patients (47.4%) (Table 1).

Thirteen cases (68.4%) had a history of traffic accidents, whereas 5 cases (26.4%) reported a history of motorcycle accidents. One case (5.2%) was admitted to the emergency room because of an occupational accident (Table 1).

The average surgical duration (from incision to closure) was 46±5 minutes, and the length of hospital stay ranged from 4±1 days. During the 3-month follow-up, accompanying additional injuries were observed to prolong the hospitalization time.

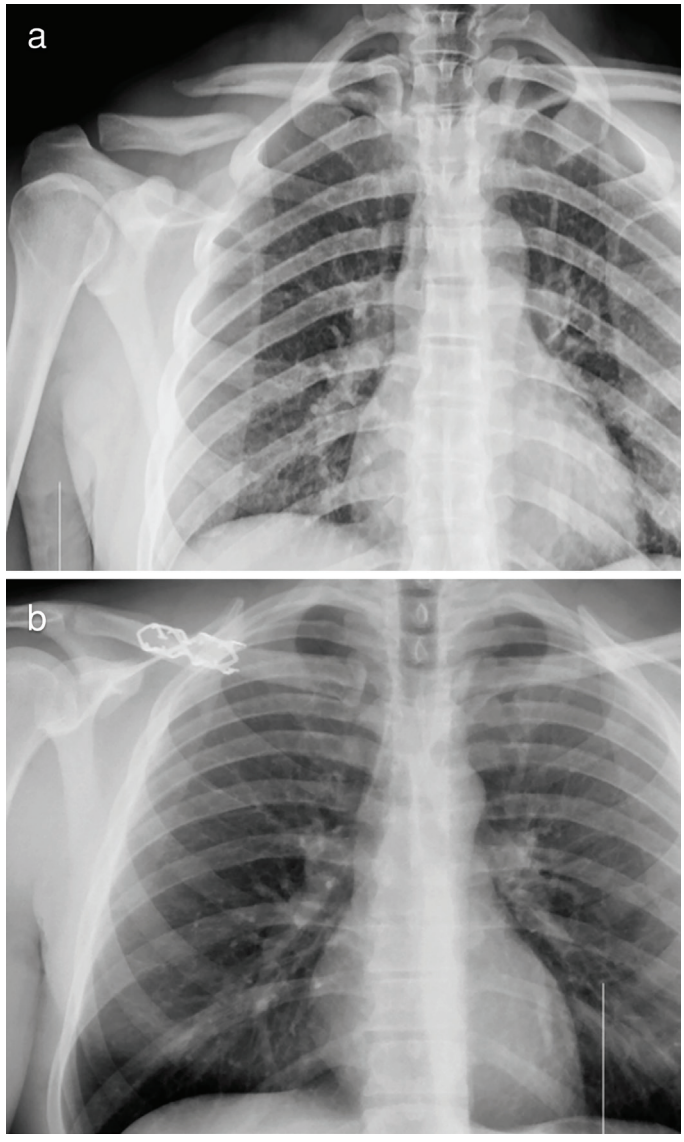

Figure 1. a) Preoperative postero-anterior chest radiography. b) Postoperative postero-anterior chest radiography

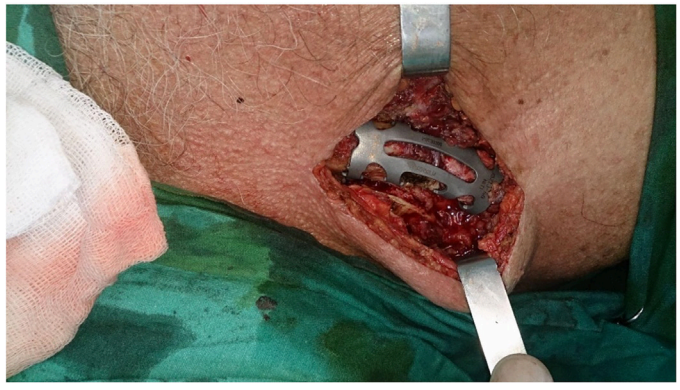

Figure 2. Intraoperative Imaging. The image shows fixation of a right clavicle fracture using nitinol plates on a posteroanterior chest radiography

Table 1. Demographic features	
Characteristics	**Patients**
Gender Male Female	 19 0
Mean age	40.4 (18-67)
Fracture side Left Right	 9 (47.4%) 10 (52.6%)
Middle third of clavicle fracture	19
Nitinol plates	19
Traffic accidents	13 (68.4%)
Motorcycle accidents	5 (26.4%)
Occupational accident	1 (5.2%)

After 3 months, one patient developed a complication. The plate lags became disconnected from the clavicle and could be palpated through the overly tense skin. Radiological evaluation revealed union at the fracture line. Consequently, additional treatment was deemed unnecessary, and the plate was subsequently removed.

Discussion

Conservative treatment methods, such as simple arm slings and figure-of-eight bandages, are commonly used for the nonsurgical management of clavicle fractures. However, the success of these methods, particularly in cases of displaced and comminuted fractures, may be limited. The occurrence of complications such as shoulder movement restriction or persistent pain often prompts a shift toward surgical intervention (5). Numerous studies have identified risk factors for nonunion fractures, including old age, female gender, comminuted fractures, and clavicle shortening exceeding 2 cm after fracture (6,7).

Considering these risk factors, surgical treatment becomes a consideration for fractures prone to non-union or malunion. Malunion resulting from conservative treatment in patients with right displaced mid-shaft clavicle fractures may lead to thoracic outlet syndrome (TOS), as suggested by some studies (4). Instances of neurogenic TOS due to clavicle malunion have also been reported (8).

Surgical intervention, particularly using nitinol plates, is preferred for midshaft fractures of the clavicle (3). Various material options, including plaques and intramedullary implants, are available for surgical treatment. A randomized controlled study involving 132 patients advocated primary plate fixation in completely displaced midshaft clavicle fractures (9).

Studies suggest that plate application promotes faster healing, especially in multi-part fractures (10). Existing literature indicates that primary surgical fixation enables a more rapid functional recovery, particularly in patients with displaced fractures (11).

While the need for further studies with larger patient cohorts is evident, our study suggests that the surgical procedure conducted with a nitinol plate can be successfully applied in selected cases. This approach is characterized by minimal dissection, short operation time, and low complication rates.

Study Limitations

However, our study's limitations are the small number of participants and the absence of a control group.

Careful surgical planning is crucial for accurately assessing the fracture pattern and ensuring the correct surgical approach.

Conclusion

Surgical treatment, although an invasive method with inherent complications, demonstrates significant success following rigorous radiological and clinical evaluations. The potential complications associated with conservative methods, especially in displaced clavicle fractures, such as TOS, should not be overlooked. Our research results indicate that the application of nitinol plates in the surgical treatment of displaced clavicle fractures can be successfully executed. We believe that this approach can be safely preferred in selected cases because of its minimal dissection, short operation time, and low complication rates.

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Ethics

Ethics Committee Approval: The study was approved by the University of Health Sciences Turkey, Medeniyet University, Göztepe Training and Research Hospital Ethics Committee (decision no: 2023/0603, date: 20.09.2023). This study was conducted in accordance with the principles of the Declaration of Helsinki.

Informed Consent: Retrospective study.

Authorship Contributions

Concept: A.G.A., T.Ş.E., Design: A.G.A., Data Collection or Processing: A.G.A., Analysis or Interpretation: T.Ş.E., Literature Search: T.Ş.E., Writing: A.G.A.

Conflict of Interest: No conflicts of interest were declared by the authors.

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Impact of the COVID-19 Pandemic on the Use of Public Access Defibrillation Systems: A Systematic Review and Meta-analysis

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Abstract

Aim: This meta-analysis presented the impact of pandemic Coronavirus disease-2019 on the use of the public access defibrillation (PAD) system for adult patients with out-of-hospital cardiac arrest.

Materials and Methods: This study was designed as a systematic review and meta-analysis and is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines. We systematically searched PubMed, Medline, Embase, and the Cochrane Central Register of Controlled Trials databases until January 2024.

Results: This meta-analysis included 30 analyzed studies. Pooled analysis showed that activation of PAD among those two periods varied and amounted to 3.8% vs. 3.9%, respectively [odds ratio (OR)=0.77; 95% confidence interval (CI): 0.66 to 0.89; p<0.001]. There were no statistically significant differences in defibrillation using automated external defibrillators (AEDs) when comparing the pandemic period with the pre-pandemic period (5.0% vs. 6.2%; OR=0.78; 95% CI: 0.57 to 1.07; p=0.12).

Conclusion: The data indicate a substantial decrease in the activation of PAD during the pandemic. Furthermore, there were no statistically significant variations in the usage of shock using AEDs, suggesting that the use of AEDs remained similar to that in the pre-pandemic periods when they were available. It is essential to promote the usage of AEDs among bystanders and perform societal initiatives to achieve this objective.

Keywords: Automated external defibrillator, AED, public access defibrillation, SARS-CoV-2, COVID-19, pandemic

Introduction

The global outbreak of Coronavirus disease-2019 (COVID-19) has precipitated profound changes in healthcare systems, with far-reaching effects on emergency medical practices (1-3). Among the most critical impacts has been the management of out-of-hospital cardiac arrest (OHCA), a medical emergency that depends on prompt and effective intervention to improve survival rates (4,5). OHCA's unique nature demands immediate recognition and swift action, often in the form of cardiopulmonary resuscitation (CPR) and the use of public access defibrillation (PAD) systems by bystanders, before professional healthcare services can arrive. These PAD systems are strategically placed in public areas to allow rapid defibrillation, a key intervention that can significantly increase the chances of survival after cardiac arrest (6).

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However, the pandemic has introduced new challenges to the management of OHCA. First, the pervasive fear of contagion has made the public hesitant to perform CPR on strangers, primarily due to the close physical contact required during the resuscitation process (7). The requirement for mouth-to-mouth ventilation, a step that is necessary for effective CPR but also presents a risk for the spread of coronavirus, has made this reluctance worse. Additionally, the extensive public health restrictions and lockdowns implemented at the pandemic's peak further limited the public's ability to respond to emergencies (8). Training opportunities for CPR and PAD use were curtailed, and potential responders may have been less likely to access PAD devices because of movement restrictions or closures of the facilities where such devices are housed.

Research has highlighted these trends, suggesting a troubling decline in the engagement of laypeople in life-saving efforts during cardiac emergencies. With PAD systems' efficacy heavily reliant on public intervention, the pandemic's social distancing measures and the associated decline in public training and willingness to engage in rescue efforts have led to concerns about the system's underutilization during critical moments. These factors have created a ripple effect, potentially diminishing the overall effectiveness of emergency response systems for OHCA and thereby affecting survival outcomes. Such developments underscore the need for innovative solutions to ensure that the public remains equipped and willing to act despite cardiac emergencies, even during periods of widespread health crises (9).

The pandemic's effect on OHCA outcomes was observed not only in areas with high COVID-19 mortality rates but also in regions with lower rates of infection. For instance, the United States experienced lower rates of sustained return of spontaneous circulation (ROSC) during the pandemic across various communities, regardless of the local COVID-19 mortality rate. This suggests a broader systemic impact rather than isolated incidents confined to high-burden areas (10).

A retrospective observational cohort study in Italy looked at the time after the pandemic and found that the chances of getting bystander CPR and PAD were back to where they were before the pandemic, but the chances of ROSC decreased significantly. This pointed toward a partial recovery of the OHCA management system but also highlighted the need for a deeper understanding of the pandemic's long-term impact on emergency medical services and the public's willingness to engage in resuscitation efforts (9).

To the best of our knowledge, no meta-analysis has been conducted so far to address the activation of PAD and the use of automated external defibrillator (AED) to perform defibrillation during COVID-19 pandemic vs. pre-pandemic periods. Therefore, this meta-analysis presented the impact of pandemic COVID-19 on the use of the PAD system for adult patients with OHCA.

Materials and Methods

The present systematic review and meta-analysis were conducted in accordance with recommendations from the Cochrane Collaboration and are reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines (11). Registration was completed on the International Prospective Register of Systematic Reviews platform with the number CRD42024500146.

Systematic reviews and meta-analyses do not require approval by institutional review committees, nor do study subjects should reconsent, and this was therefore not sought.

Data Sources and Searches

Two authors (AK and KK) independently conducted the literature search. According to the recommendations from the Cochrane Handbook for Systematic Reviews for meta-analysis, we implemented a systematic literature search in PubMed, Medline, Embase, and the Cochrane Central Register of Controlled Trials databases for articles comparing OHCA in pandemic and pre-pandemic periods which were published between the inception dates (January 2020) and January 2024. We used Boolean logic to create the search phrase: "heart arrest" OR "cardiac arrest" OR "cardiac arrest" OR "out-of-hospital cardiac arrest" OR "OHCA" OR "OOHCA" OR "OH-CA" OR "sudden cardiac death" AND "automatic external defibrillator" OR "automated external defibrillator" OR "defibrillator" OR "defibrillation" OR "AED" OR "public access defibrillation" OR "PAD" AND "coronavirus" OR "COVID" OR "COVID 19" OR "COVID-19" OR "Coronavirus disease 2019" OR "nCOV" OR "SARS-CoV2" OR "severe-acute-respiratory-syndrome-related coronavirus 2". We also manually searched the reference lists of the included studies to identify additional eligible studies.

Inclusion and Exclusion Criteria

The inclusion criteria were as follows: (1) study population: adult patients with OHCA; (2) studies reporting PAD activation or shock with AED during pandemic and pre-pandemic periods; and (5) study type: randomized and non-randomized trials. The exclusion criteria encompassed the following: (1) narrative reviews, commentaries, editorials, case series, conference abstracts, and correspondence letters; (2) duplicated publications; (3) literature in languages other than English; (4) pediatric patients or patients with in-hospital cardiac arrest (IHCA); and (5) texts where the full manuscript was not available.

Literature Screening and Data Extraction

Following the literature search, two reviewers independently examined the titles, abstracts, and keywords of the articles to determine their eligibility based on the predefined inclusion criteria. Subsequently, these reviewers conducted a thorough review of the full texts of the initially selected studies, excluding those that did not fulfill the stipulated exclusion criteria (AK and DK). Instances of disagreement were reconciled through collaborative discussion with a third investigator (KK). Extracts included: study title, first author, year of publication, country, patient characteristics (age, sex, home location of cardiac arrest), resuscitation characteristics (witnessed arrest, bystander CPR, PAD activation, shock with AED, shockable rhythm, EMS activation time, time to first defibrillation, survival to hospital admission (SHA), survival to hospital discharge (SHD) and SHD with good neurological outcome-defined as a score 1 or 2 in Cerebral Performance Categories Scale).

Risk of Bias Assessment

The assessment of the risk of bias in the included studies was independently conducted by two authors (AK and MT). During the quality assessment of the included studies, any disagreements were resolved by consensus with the third reviewer (LS). The Newcastle-Ottawa scale was used for this purpose (12). This scale is segmented into three categories: selection, comparability, and outcome, and is further subdivided into eight items, yielding a total possible score ranging from 0 to 9. Studies that attained a score of 7 or higher were categorized as high quality. Detailed information regarding the risk of bias assessment is presented in Table 1.

Statistical Analysis

The statistical analysis adhered to the guidelines set forth by the Cochrane Collaboration and the standards for reporting meta-analyses' quality (13). The Review Manager software (version 5.4, Nordic Cochrane Centre, Cochrane Collaboration, Denmark) and Stata (version 14, StataCorp, College Station, TX, USA) were used for statistical computations. Analyses were two-tailed with statistical significance set at $p<0.05$. The outcomes were articulated as pooled odds ratios (OR), mean differences, and their respective 95% confidence intervals (95% CI). For instances where continuous outcomes were presented as medians, ranges, and interquartile ranges, means and standard deviations were estimated using the methodology proposed by Hozo et al. (14). Heterogeneity among studies was quantitatively evaluated using the I2 statistic, with I2 values of 50%, 50-75%, and >75% indicating low, moderate, and high heterogeneity, respectively (15). If the results of each study showed that $I^2 \leq 50\%$ and $p>0.1$, indicating that the heterogeneity between studies was not statistically significant, the Mantel-Haenszel fixed-effects model was selected for meta-analysis; otherwise, the DerSimonian-Laird random-effects model was selected for meta-analysis. Assessment for potential bias was conducted using Egger's test and funnel plots (16), with funnel plot tests for asymmetry being applied to evaluate possible publication bias in cases where a meta-analysis included more than 10 trials (17). In addition, sensitivity analyses were conducted using the leave-one-out approach.

Results

Selected Studies

The PRISMA flow diagram of the literature search and study selection of our meta-analysis is depicted in Figure 1. Of the 733 identified records, 381 studies were screened after duplicate removal. This led to the eligibility assessment of 48 studies, of which 30 studies comprising were included in further analyses (9,10,18-45). The aforementioned papers were then incorporated into the meta-analysis. Among those articles, three provided data on both PAD activation and shock with AED, while the other 21 and six articles only mentioned information on PAD activation and shock with AED, respectively (Figure 2).

Baseline Characteristics

This meta-analysis included 30 analyzed studies with a combined cohort of 127,045 patients, of which 27 were retrospective studies and 3 were prospective studies. The global distribution

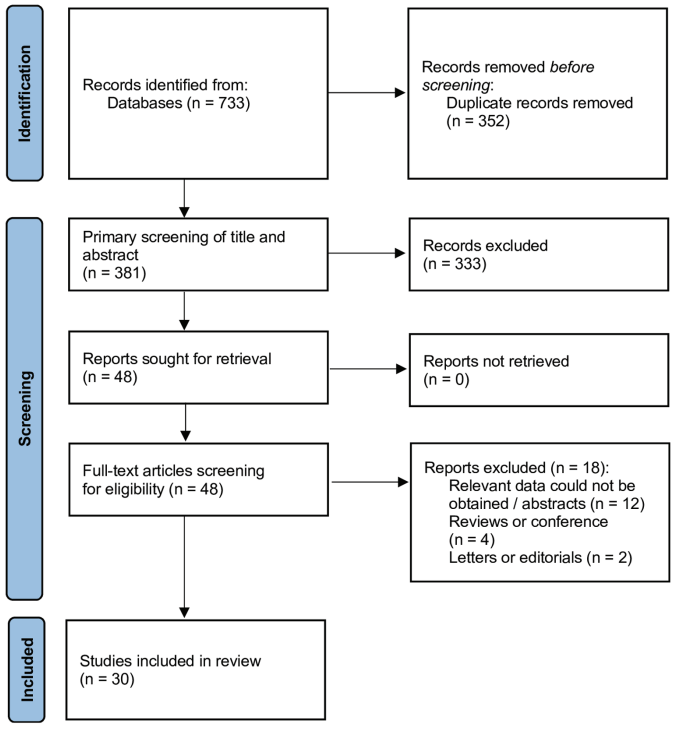

Figure 1. PRISMA flowchart

Table 1. Baseline characteristics of the included trials

Study	Country	Study design	Pandemic period			Pre-pandemic period			NOS score
			No.	Age, years	Sex, male	No.	Age, years	Sex, male	
Ahn et al., 2021 (18)	Korea	PS	152	74.9±2.6	102 (67.1%)	145	72.9±3.4	91 (62.8%)	8
Baert et al., 2020 (19)	France	RS	1005	68±17	676 (67.3%)	1620	69±17	1071 (66.1%)	8
Baldi et al., 2021 (20)	Switzerland	RS	911	69±4	623 (68.4%)	933	70.5±4	636 (68.2%)	8
Chan et al., 2021 (10)	USA	PS	9863	62.6 (19.3)	6040 (61.3%)	9440	62.2±19.2	5922 (62.7%)	8
Chavez et al., 2022 (21)	USA	RS	4418	63 (51-74)	2781 (62.9%)	3619	63 (51-74)	2307 (63.8%)	8
Cho et al., 2020 (22)	Korea	RS	171	74 (62-80)	108 (63.2%)	158	74.3 (61.8-82.2)	103 (65.2%)	8
Chugh et al., 2023 (23)	USA	PS	907	69.5±17.0	586 (64.6%)	1315	71.3±15.8	857 (65.2%)	8
Fothergill et al., 2021 (24)	UK	RS	3122	71±19	1839 (59.0%)	1724	68±20	1069 (62.0%)	8
Gregers et al., 2022 (25)	Denmark	RS	74	74±16	5067.6%)	182	74±18	117 (62.3%)	7
Huabbangyang et al., 2023 (26)	Thailand	RS	482	65.18±18.16	304 (63.1%)	513	64.18±19.94	320 (62.4%)	8
Leung et al., 2023 (27)	China	RS	2185	77.69±4.18	1880 (86.0%)	1502	78 (63-88)	844 (56.2%)	8
Lim et al., 2021 (28)	Singapore	RS	1400	73 (60-84)	882 (63.0%)	2493	71.01±3.84	1597 (64.1%)	8
Lim et al., 2021 (B) (29)	Singapore	RS	1063	71.05±14.98	647 (60.87%)	891	70.07±15.06	577 (64.76%)	8
Lim et al., 2022 (30)	International	PS	2084	69.02±5.21	1235 (59.3%)	1900	68.79±4.86	1161 (61.1%)	8
Liu et al., 2023 (31)	Taiwan	RS	497	78 (65-85)	292 (59.0%)	567	76 (64-85)	313 (55.4%)	8
Liu et al., 2023 (B) (32)	USA	RS	3142	63 (51-75)	2005 (63.8%)	2837	64 (52-75)	1859 (65.5%)	8
Nishiyama et al., 2022 (33)	Japan	RS	2371	80 (70-87)	1384 (58.4%)	2420	78 (68-86)	1403 (58.0%)	8
Oh and Ahn, 2023 (34)	Korea	RS	9240	60.0±17.3	1868 (20.2%)	22,897	59.1±17.5	5024 (21.9%)	8
Riyapan et al., 2022 (35)	Thailand	RS	350	63.4±19.4	208 (59.4%)	341	62.7±18.5	210 (61.6%)	8
Rosell Ortiz et al., 2020 (36)	Sapin	RS	1446	64.36±16.5	1028 (71.1%)	1723	65.61 (16.9)	1210 (70.2%)	9
Shibahashi et al., 2022 (37)	Japan	RS	3109	NS	1778 (57.2%)	3234	NS	1868 (67.8%)	8
Stirparo et al., 2023 (9)	Italy	RS	1767	NS	NS	1097	NS	NS	7
Sugiyama et al., 2023 (38)	Japan	RS	1730	66±17.33	108 (58.8%)	1637	66.3±17.5	918 (56.1%)	9
Sultanian et al., 2021 (39)	Sweden	RS	1016	69.6±17.8	697 (68.6%)	930	70.8 (16.6)	604 (64.9%)	9
Sun et al., 2021 (40)	USA	RS	298	NS	NS	220	NS	NS	7
Talikowska et al., 2021 (41)	Australia	RS	145	61 (46-74)	101 (69.7%)	501	60 (46-74)	345 (68.9%)	8
Tanaka et al., 2024 (42)	Japan	PS	5023	76 (62-84)	3095 (61.6%)	2015	72 (62-84)	1236 (61.4)	8
Uy-Evanado et al., 2021 (43)	USA	RS	278	64.9±18.3	174 (62.6%)	231	69.1±17.4	137 (78.7%)	8
Watanabe et al., 2023 (44)	Japan	RS	257	76.46±15.32	161 (62.6%)	262	75.47±16.31	160 (61.1%)	8
Yu et al., 2021 (45)	Taiwan	RS	622	70.41±16.21	394 (63.3%)	570	70.93 (16.45)	353 (61.9%)	8

NS: Not specified, PS: Prospective study, RS: Retrospective study

of the original studies included in the meta-analysis is presented in Figure 3. The baseline patient characteristics of the included studies are summarized in Table 1. According to the Newcastle Ottawa Scale, all studies were of high quality. The risk of bias assessment for the included studies is described in Table 1. The full characteristics related to resuscitation are shown in Table 2.

Outcomes

Twenty-four studies reported PAD activation during pandemic and pre-pandemic periods. Pooled analysis showed that activation of PAD among those two periods varied and amounted to 3.8% vs. 3.9%, respectively (OR=0.77; 95% CI: 0.66 to 0.89; p<0.001; Figure 4).

In contrast, there were no statistically significant differences in defibrillation using AEDs when comparing the pandemic period with the pre-pandemic period (5.0% vs. 6.2%; OR=0.78; 95% CI: 0.57 to 1.07; p=0.12; Figure 5).

Discussion

This systematic review and meta-analysis presents intriguing findings regarding PAD activation and AED use during the

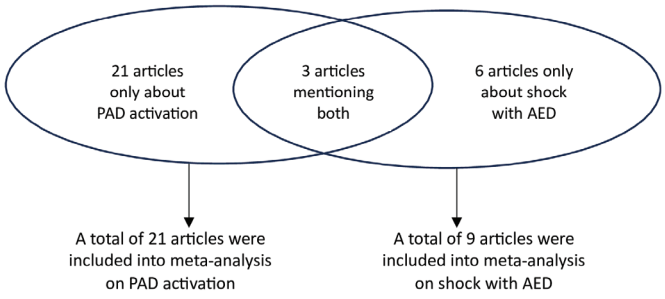

Figure 2. The number and distribution of articles used in the meta-analysis on PAD activation and defibrillation with AED

PAD: Public access defibrillation, AED: Automated external defibrillators

COVID-19 pandemic. The pooled analysis showing PAD activation rates of 3.8% during the pandemic versus 3.9% in the pre-pandemic period, with an OR of 0.77, suggests a slight but statistically significant decrease in PAD activation during the pandemic. This decrease can be attributed to various factors associated with the pandemic, such as reduced public mobility and access to areas where PADs are typically located, as indicated by most AEDs becoming inaccessible due to government-mandated closures during the pandemic (46).

On the other hand, the absence of statistically significant differences in shock with AED (5.0% during the pandemic vs. 6.2% pre-pandemic; OR=0.78) suggests that when AEDs were accessible, their use was not markedly different from pre-pandemic times. This observation might reflect the ongoing effectiveness of public education campaigns and the ingrained public response to cardiac emergencies, even under pandemic conditions (47). The pandemic also significantly shifted public attitudes toward CPR and publicly accessible defibrillator use. Hawkes et al. (47) noted that national initiatives led to an increase in the number of people trained in CPR, which correlated with improved bystander CPR rates and OHCA outcomes. Inaba et al.'s (48) study further examined the pandemic's impact on bystander reactions to OHCA, underscoring how public response to cardiac emergencies evolved during this period. Moreover, a study conducted in the United Kingdom focused on the early defibrillation aspect of OHCA management during the pandemic, emphasizing its essential role in the survival chain for such emergencies (47). This was complemented by many meta-analyses that compared the epidemiological characteristics and outcomes of OHCA during the COVID-19 pandemic with those during the pre-pandemic period (49-51). Overall, these studies collectively underscore the significant influence of the COVID-19 pandemic on various facets of OHCA management, from public response and PAD usage to the clinical outcomes of these critical events. There are conflicting studies on changes in the witnessed use of CPR and AEDs, indicating that this may have varied by region and specific pandemic conditions (52). Overall, despite pandemic-induced changes in the availability and use of AEDs, their effectiveness and frequency of use remained similar.

Despite an increase in the frequency of witnessed CPR during the COVID-19 pandemic (53) and a slight decrease in PAD activation while maintaining the frequency of defibrillation using AEDs, the analysis of the scientific literature allows us to conclude that COVID-19 had an adverse effect on the survival of patients with both OHCA and IHCA. One of the critical aspects of COVID-19's impact is the emergence of coagulopathy associated with the virus, known as COVID-19-associated coagulopathy. This condition is characterized by a state of hypercoagulability,

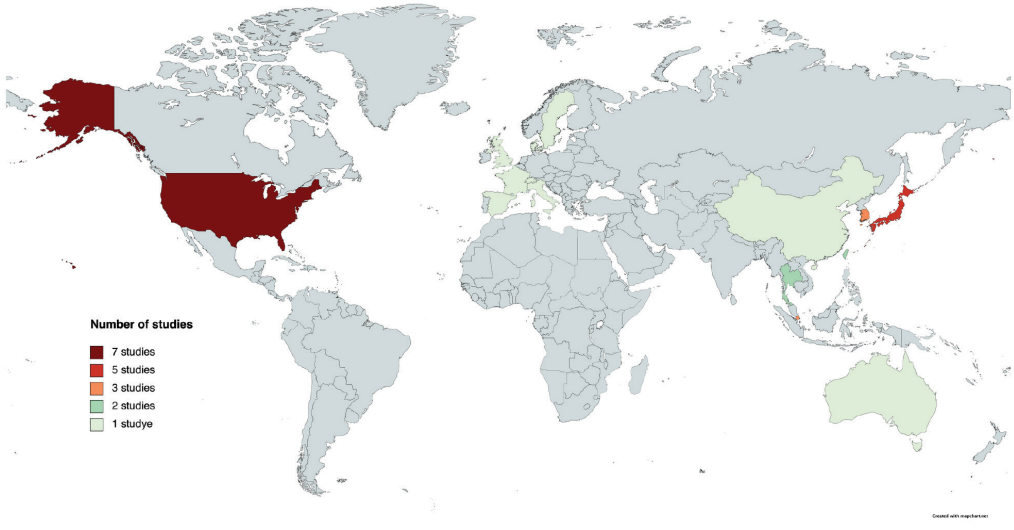

Figure 3. Global distribution of articles included in the meta-analysis

Table 2. Baseline patient characteristics and resuscitation characteristics among included trials

Parameter	Number of studies	Event/participants of mean±SD		Events		Heterogeneity between trials		P value for differences across groups
		Pandemic period	Control period	OR or MD	95% CI	p value	I2 statistics	
Age, years	27	66.8±15.2	64.4±16.1	0.30	-0.19 to 0.79	<0.001	97%	0.22
Sex, male	29	31,798/57,181	32,576/67,033	1.07	0.99 to 1.17	<0.001	89%	0.10
Home location of cardiac arrest	25	31,456/42,092	26,885/38,568	1.23	1.12 to 1.34	<0.001	85%	**<0.001**
Witnessed arrest	27	24,435/49,965 (48.9%)	29,618/61,742 (48.0%)	1.23	1.05 to 1.44	<0.001	97%	**0.01**
Bystander CPR	30	24,801/56,590 (43.8%)	25,737/66,934 (38.5%)	1.09	0.96 to 1.24	<0.001	96%	0.18
Shockable rhythm	26	7298/48,596	10,313/6,700	0.95	0.92 to 0.99	0.02	41%	**0.007**
EMS response time, min	21	9.9 (4.9)	9.5 (5.0)	1.03	0.75 to 1.31	<0.001	100%	**<0.001**
First defibrillation time, min	3	14.7 (4.9)	12.5 (4.3)	2.66	1.28 to 4.04	<0.001	99%	**<0.001**
SHA	26	9818/51,391	15,615/61,032	0.72	0.64 to 0.81	<0.001	91%	**<0.001**
SHD	25	3895/52,174	6848/61,711	0.64	0.57 to 0.71	<0.001	76%	**<0.001**
SHD with a good neurological outcome	17	1860/36.242	3288/45,530	0.68	0.59 to 0.77	<0.001	60%	**<0.001**

CI: Confidence interval, CPR: Cardiopulmonary resuscitation, EMS: Emergency medical service, MD: Mean difference, OR: Odds ratio, SHA: Survival to hospital admission, SHD: Survival to hospital discharge

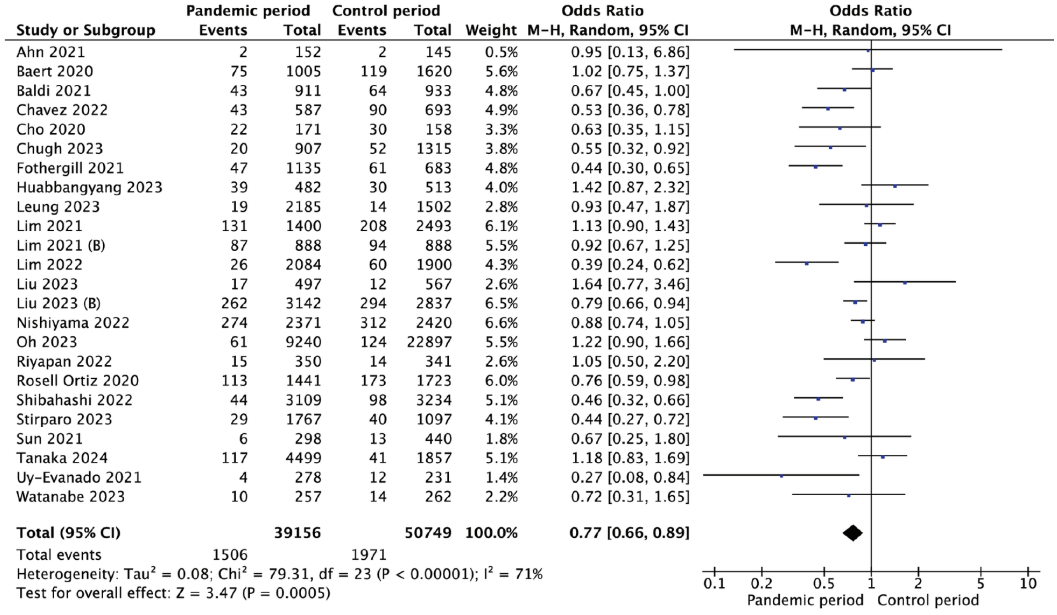

Figure 4. Forest plot of PAD ratio among COVID-19 pandemic vs. pre-pandemic periods. The center of each square represents the odds ratios for individual trials, and the corresponding horizontal line stands for a 95% confidence interval. The diamonds represent pooled results

PAD: Public access defibrillation, COVID-19: Coronavirus disease-2019, CI: Confidence interval

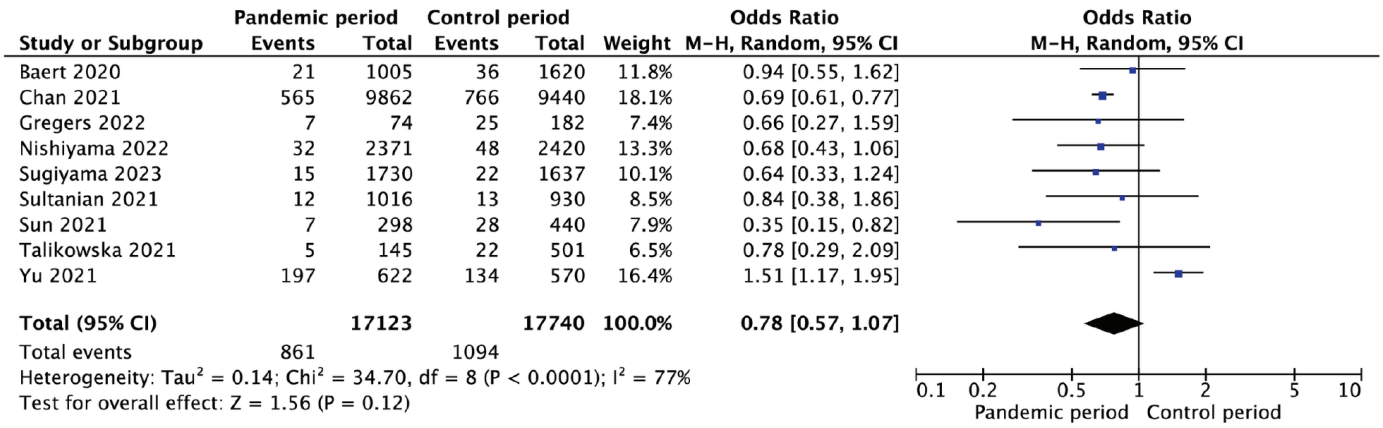

Figure 5. Forest plot of defibrillation with AED among COVID-19 pandemic vs. pre-pandemic periods. The center of each square represents the odds ratios for individual trials, and the corresponding horizontal line stands for a 95% confidence interval. The diamonds represent pooled results

AED: Automated external defibrillators, COVID-19: Coronavirus disease-2019, CI: Confidence interval

which contributes to the severity and complications in infected patients, including an increased risk of thrombotic events (54-56). Additionally, the pandemic has led to a dramatic reduction in the availability of healthcare for seniors, particularly concerning the access and restructuring of different hospital departments (57). This reduction in healthcare accessibility has profound implications for patient outcomes, particularly for the elderly who are already at higher risk of developing COVID-19.

Another point worth emphasizing here-even though it is not the immediate focus of this study-is the impact of increased EMS response time during a pandemic. The rapid response of emergency medical teams is crucial for increasing the chances of survival in OHCA cases, where the optimal response time is usually a few minutes after the event. However, during a pandemic, many emergency medical systems experienced delays because of additional safety procedures, such as the need for staff to wear appropriate protective gear, and because of the increased burden on health systems. These delays in response directly impact the effectiveness of resuscitation. Therefore, early defibrillation and advanced CPR are key to improving the prognosis of OHCA. Delays in initiating CPR can limit the duration of the therapeutic window, which is critical to the effectiveness of these interventions. When emergency medical teams arrive late, the likelihood of resuscitation success decreases significantly. Finally, the overall greater strain on health systems caused by the pandemic may have contributed to a slower response to medical emergencies. Hospitals and emergency teams are often overburdened with treating patients with COVID-19, affecting availability and responsiveness to emergencies such as OHCA. As a result, the COVID-19 pandemic led to increased response times for emergency medical teams, which had a direct impact on reduced survival rates in OHCA cases. This increase in response time, coupled with delays in access to key resuscitation interventions, reduced witness readiness to provide first aid, and overall strain on health systems, is a key factor in the lower survival rates for OHCA cases during the pandemic.

Study Limitations

The primary limitations of our study relate to the limitations of the studies and data included in our systematic review and meta-analysis. This comprehensive review and meta-analysis used data from 15 countries and did not include any studies conducted in Africa or South America. In addition, European studies mostly concentrated on nations located in Western Europe. The limitations inherent in this study present difficulties generalizing the results worldwide. Moreover, it is important to acknowledge that the introduction of COVID-19 vaccines and notable viral subvariants might have had a considerable influence on the course of the pandemic. Nevertheless, it is crucial to emphasize that none of the studies included in the meta-analysis focused on this topic. This work is a comprehensive analysis and synthesis of previously published non-randomized controlled trials conducted methodically. Nevertheless, its ability to depict overall patterns is restricted.

Conclusion

These data indicate a substantial decrease in the activation of PAD during the pandemic. Furthermore, there were no statistically significant variations in the usage of shock using AEDs, suggesting that the use of AEDs remained similar to that

in the pre-pandemic periods when they were available. It is essential to promote the usage of AEDs among bystanders and perform societal initiatives to achieve this objective.

Ethics

Ethics Committee Approval and Informed Consent: Systematic reviews and meta-analysis do not require approval by institutional review committees, nor do study subjects need to reconsent and this was therefore not sought.

Authorship Contributions

Concept: A.K., Design: A.K., M.T., Data Collection or Processing: A.K., F.C., Analysis or Interpretation: A.K., A.G-K., Literature Search: A.K., D,K., A.G-K., F.C., M.P., Writing: A.K., D,K., A.G-K., N.L.B., F.C., M.P., B.C., M.T., S.G., L.S., K.K.

Conflict of Interest: No conflict of interest was declared by the authors.

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Breaking the Cycle: How Physical Therapy Modalities Impact Emergency Department Visits in Patients with Chronic Low Back Pain

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Abstract

Aim: Low back pain (LBP) is a common health problem worldwide and ranks among the top ten reasons for emergency department (ED) visits, although most cases do not require immediate care. This study aimed to compare ED visits for LBP during a 6-month follow-up period between patients receiving a home-based exercise program and those receiving additional physical therapy (PT) modalities, exploring a previously uninvestigated aspect.

Materials and Methods: This retrospective study included 419 patients with chronic LBP treated at the Department of Physical Medicine and Rehabilitation from July 2021 to January 2023. Patients were divided into two groups: those who received a home-based exercise program and those who received PT modalities in addition to exercise programs. Using appropriate statistical methods, the two groups were analyzed for their ED visits and potential influencing factors during a 6-month follow-up period. $p<0.05$ was accepted as statistically significant.

Results: Patients receiving physiotherapy had significantly fewer ED visits during the 6-month follow-up period ($p=0.001$). No association was observed between ED visits and patient demographics.

Conclusion: The study demonstrated that integrating PT modalities into the management of chronic LBP resulted in fewer ED visits.

Keywords: Emergency department, low back pain, physical therapy

Introduction

Low back pain (LBP) is conventionally characterized as discomfort, muscular constriction, or rigidity localized to the anatomical region below the costal margin and superior to the inferior gluteal creases (1). Pain persisting for more than 12 weeks is defined as chronic LBP (2). The prevalence of chronic LBP varies among studies; however, one study conducted in a geographic area close to our study area reported a prevalence rate of 13.1% (3). LBP is one of the most common reasons for emergency department (ED) visits, although most cases do not require immediate or urgent care (4,5).

The treatment of LBP remains a challenge for clinicians (6). A systematic review of the guidelines strongly recommends patient education, advice to stay active, return-to-work programs, exercise programs/therapy, psychological therapies, multidisciplinary treatment, and surgical options for specific groups (7). However, it is noteworthy that more than two-thirds of patients with LBP experience a recurrence within one year of improvement (8). Physical therapy (PT) modalities are among the most commonly used conservative treatments for LBP (9). Numerous studies that combine exercise with PT modalities have consistently demonstrated their beneficial effects on pain relief, functionality improvement, reduction of disability, and mitigation of psychological disorders (9-13). However, in our comprehensive

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literature review, there was no prior investigation of their impact on ED visits. The aim of this study was to compare ED visits for LBP during the 6-month follow-up period between patients who received a home-based exercise program and those who received PT modalities consisting of hot pack (HP), therapeutic ultrasound (US), and transcutaneous electrical nerve stimulation (TENS) in addition to the home-based exercise program.

Materials and Methods

Study population: This retrospective study included patients with chronic mechanical LBP who were treated at the Department of Physical Medicine and Rehabilitation of our hospital between July 2021 and January 2023.

Patients were included if they met the following criteria: (a) documented history of chronic mechanical LBP persisting for at least 12 weeks, (b) age >18 years, and (c) diagnosis confirmed by lumbar magnetic resonance imaging. Patients with any of the following conditions were excluded: (a) severe systemic diseases, (b) malignancies, (c) vertebral fractures, (d) neurological deficits, (e) history of spinal surgeries, (f) pregnancy, (g) inflammatory rheumatic disorders, and (h) low back trauma within the last 6 months. Moreover, patients who did not complete 10 sessions in the PT group were also excluded from the study. Demographics including age and gender were recorded, and details of ED visits during the 6-month post-treatment period. Pain assessments of the patients were retrospectively conducted by reviewing the data collected using the Numerical Rating Scale (NRS).

A total of 121 patients were excluded from the study for the following specified reasons: 44 patients had ankylosing spondylitis, 25 patients reported a history of lumbar surgery, 17 patients had neurological deficits, 5 patients had rheumatoid arthritis, 4 patients had Behçet's syndrome, 3 patients had recent trauma history within the last 6 months, 3 patients had spine fractures, 3 patients were under the age of 18, 3 patients had lumbar mass, 2 patients had systemic malignancy, 2 patients had familial mediterranean fever, 1 patient had myasthenia gravis, 1 patient had psoriatic arthritis, 1 patient had amyotrophic lateral sclerosis, 1 patient had scleroderma, 1 patient had sarcoidosis, 1 patient had severe chronic kidney disease, 1 patient had split cord malformation, 1 patient had severe heart failure, 1 patient had severe Parkinson's disease, 1 patient was diagnosed with Still's disease. Finally, 419 patients were included in the study.

Treatment modalities: A subset of patients received a home-based exercise program, whereas others received PT modalities that included HP, US, and TENS in addition to the home-based exercise program. HP therapy sessions lasted 20 min. US therapy was administered continuously for 6 min at a frequency of 1 MHz and a power density of 1.5 W/cm². TENS therapy was applied continuously for 30 min at a frequency of 100 Hz and a pulse duration of 40 μs. The number of sessions ranged from 10 to 15 because of the retrospective nature of the study.

Individualized home-based exercise programs were prescribed to each patient, accounting for their unique medical conditions. These programs typically comprise strengthening exercises for the abdominal and lumbar muscles and stretching exercises for the hip flexors and lumbar extensors. Patients were instructed to perform these exercises for a minimum of 5 days per week. Written instructions for the exercise program were provided, and any exercises that the patients had difficulty comprehending were explained in detail by a physiotherapist.

Statistical Analysis

Statistical analyses were conducted using IBM Statistical Package for the Social Sciences statistics version 22 software (IBM, Armonk, New York, USA). Descriptive statistics were expressed as mean and standard deviation or median and interquartile range or percentile, as appropriate. A p value of 0.05 was considered statistically significant. Normal distribution of the data was analyzed using the Kolmogorov-Smirnov test. Comparisons of age and body mass index between the groups were performed using independent samples t-tests. Differences in gender distribution, smoking habits, presence of comorbidities, and the presence of visiting the ED within a 6-month period were assessed using chi-square tests. To analyze the number of ED visits, the Mann-Whitney U test was used to evaluate differences between the PT and control groups. This test was also employed to assess differences in NRS scores between the groups. Within each group, changes in NRS scores over time were analyzed using the Wilcoxon signed-rank test. Furthermore, in the subgroup of participants assigned to a home-based exercise regimen, the association between ED visits and various factors, including comorbidities and gender, was examined using chi-square tests. The relationship between the presence of ED visit and age was explored using Student's t-test. Finally, the correlation between the number of ED visits and patient age was explored using Spearman's rank correlation coefficient, denoted as Spearman's rho.

Results

A total of 419 patients were enrolled in this study. Of these, 110 patients received PT modalities in conjunction with home-based exercise programs, whereas the remaining 309 patients received exclusive home-based exercise programs. A flowchart of the study is shown in Figure 1. In our comparative analysis of the two groups, demographic characteristics and comorbidities were

closely examined. The only difference that emerged as statistically significant pertained to the age distribution between the groups. For a comprehensive breakdown of these data, please refer to Table 1, which provides detailed information on this aspect.

No significant differences were observed in the initial pain scores, as measured by the NRS, between the groups that received PT modalities and those that did not [median (25^{th}, 75^{th} P); 7 (5,7), 6 (5,7), p=0.204, respectively]. At the conclusion of the 6-month study period, both groups exhibited improved pain scores [PT group: median (25^{th}, 75^{th} P); baseline 7 (5,7), 6^{th} month 5 (4,6), p<0.001; exercise group median (25^{th}, 75^{th} P); baseline 6 (5,7), 6^{th} month 5 (5,7), p<0.001]. The improvement in pain scores was significantly greater in the group receiving PT (median (25^{th}, 75^{th} P); 2 (1,2), 1 (0,1), p<0.001, respectively). Detailed data on patients' pain scores are presented in Table 2.

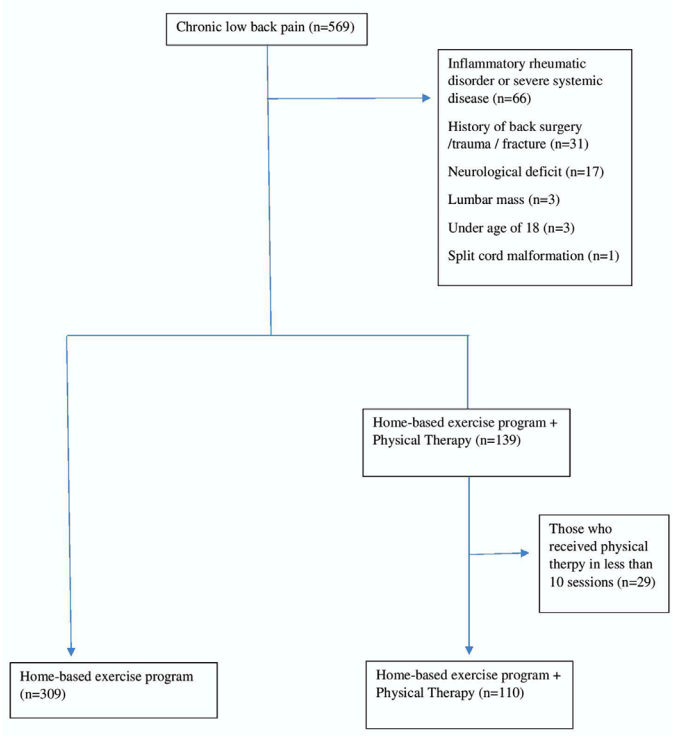

Figure 1. The flowchart of the study

During the 6-month follow-up period, patients who received PT had a statistically significant reduction in the number of ED visits compared with those who received home-based exercise therapy alone [median (25^{th}, 75^{th} P); 0 (0,0), 0 (0,0), p=0.001]. When we categorize patients into two groups, one comprising those who have not visited the ED in the past 6 months and the other comprising those who have sought ED care at least once, it becomes clear that patients receiving PT modalities tend to visit the ED significantly less frequently than those not receiving PT (p=0.013). For an in-depth understanding of this trend, Table 2 offers comparative data on ED visit frequencies, while Table 3 details the specific number of visits within each group.

Due to the limited number of ED visits in the PT group (only 6 individuals), analyzing factors influencing these visits was not feasible. In contrast, within the exercise group, the presence of comorbidities did not markedly impact the likelihood of ED admissions, with similar rates observed between individuals with at least one comorbidity (15.4%, 31 individuals) and those without any (14.8%, 16 individuals; p=0.999). Additionally, gender was not a significant factor in determining ED visits, as evidenced by 13.2% of females and 20.2% of males requiring care (p=0.166). Age also showed no significant correlation with ED visits, with comparable age distributions in those who did and did not visit the ED (45.22±13.18 vs. 48.23±13.66, respectively; p=0.167). No significant association between age and ED visit numbers was observed (CC=0.096, p=0.091).

Table 1. Demographic features and comorbidities of participants

		Home-based exercise n=309	Physical therapy + Home-based exercise n=110	p value
Age (year); mean (SD)		47.74 (13.60)	53.66 (13.54)	<0.001
BMI (kg/m^2); mean (SD)		29.63 (5.46)	29.67 (5.81)	0.953
Gender; female n (%)		220 (77%)	85 (71%)	0.262
Smoking habit; smoker n (%)		67 (22%)	25 (23%)	0.926
Comorbidities; n (%)	Hypertension	64 (20.71%)	19 (17.27%)	0.524
	Diabetes mellitus	39 (12.62%)	13 (11.82%)	0.959
	Hypothyroidism	15 (4.85%)	7 (6.36%)	0.718
	Coronary artery disease	9 (2.91%)	5 (4.55%)	0.610
	Hyperlipidemia	20 (6.47%)	8 (7.27%)	0.947
	Asthma	20 (6.47%)	5 (4.55%)	0.618

BMI: Body mass index, N: Number, SD: Standard deviation

Table 2. NRS pain scores and emergency department visits of participants			
	Home-based exercise n=309	Physical therapy + Home-based exercise n=110	p value
NRS pain score at baseline; median (IQR 25-75)	6 (5,7)	7 (5,7)	0.204
NRS pain score at 6th month; median (IQR 25-75)	5 (5,7)	5 (4,6)	<0.001
NRS pain score change between baseline and 6th month	1 (0,1)	2 (1,2)	<0.001
ED visits; median (IQR 25-75)	0 (0,0)	0 (0,0)	0.001
Visiting ED at least once within 6 month period; n (%)	47 (15.2%)	6 (5.5%)	0.013
ED: Emergency department, IQR: Interquartile range, NRS: Numerical Rating Scale, IQR: Interquartile range			

Table 3. Emergency department visits for low back pain				
	Physical therapy (n=110)		Control group (n=309)	
ED visits	Number of patients	Percentage of patients	Number of patients	Percentage of patients
0	104	94.5	262	84.8
1	3	2.7	35	11.3
2	3	2.7	8	2.6
3	-	-	3	1
4	-	-	-	-
5	-	-	1	0.3
ED: Emergency department				

Discussion

In this study, which involved 419 patients, a lower rate of ED admissions was observed in patients treated with PT modalities than in other patients. This finding underscores the importance of incorporating PT modalities into the treatment regimens of patients struggling with chronic mechanical LBP.

Although PT interventions are routinely applied to alleviate LBP in clinical practice, there remains a paucity of comprehensive investigations in this field. It is pertinent to examine comparative studies featuring relatively extensive patient cohorts. One of the first studies in this research field under consideration belongs to Koldaş Doğan et al. (10). In this study, a cohort of 60 patients was divided into three groups: the first group underwent home-based exercise and aerobic exercise, the second group received home-based exercise in conjunction with PT modalities, and the third group exclusively engaged in home-based exercise (11). Notably, all groups showed a reduction in pain; however, the treatment approach used in the second group, which is similar to our study, showed superior efficacy in improving disability and reducing psychological distress (10).

Another important investigation on this topic was conducted by Yılmaz et al. (12), in 2015, which included a cohort of 56 patients divided into two groups: an exercise-only cohort and a group that combined exercise with PT. When assessed one month after treatment, the cohort that received PT combined with exercise experienced a greater reduction in pain and an improvement in functional status (12). In a randomized controlled trial conducted by Şahin et al. (13) between February 2011 and August 2013, 104 patients were assigned to either the PT group or the control group. After one year of follow-up, the results showed superior improvements in both pain assessment scores and disability indices within the PT group compared with the control group (13). Collectively, these studies have consistently demonstrated the beneficial effects of PT on pain management, functional disability, and psychological well-being in patients with LBP. The convergence of evidence from these investigations supports our findings and further validates the alignment between our study and the prevailing body of research. It is worth noting that our study explored an additional dimension of the impact of PT, specifically its role in reducing ED visits for patients with chronic LBP. Our research clearly confirmed that PT not only alleviates pain but also contributes to a significant reduction in ED visits for this patient population.

From the perspective of the ED, the issue of overcrowding emerges as a paramount concern, primarily due to its impact on the quality of healthcare and its role in increasing the overall burden on the healthcare system (14). Considering the imperative to reduce ED visits, notably LBP ranks among the most prevalent causes for admissions to ED globally (4,15). A meta-analysis of 21 studies from 12 countries estimated the prevalence of LBP cases in EDs to be 4.39%, placing LBP in the top ten causes of ED admissions (4,15). A meta-analysis conducted by Galliker

et al. (5) in 2020 further revealed that the prevalence of cases requiring immediate or urgent treatment among patients with LBP admitted to the ED ranged from 2.5% to 5.1% in prospective studies and from 0.7% to 7.4% in retrospective studies. These figures clearly indicate that the majority of these patients do not warrant immediate or urgent intervention, thereby unnecessarily contributing to ED overcrowding.

Study Limitations

Our study's limitations are primarily rooted in its retrospective nature, which inherently limited the scope of data available for analysis. In the PT group, the small sample size (n=6) who visited the ED hindered a detailed examination of factors influencing these visits. This gap in data, especially regarding pain exacerbation circumstances and patients' working status, is a critical area for future research. The retrospective design also resulted in variability in the number of PT sessions administered. Another significant constraint was our inability to monitor patients' use of pain-relief medications outside the hospital setting, a factor that could greatly influence the decision to seek emergency care. Pain is inherently subjective, and individual decisions to seek emergency care can vary widely based on pain tolerance and personal circumstances. Regarding the observed age difference between the groups, we do not view this as a limitation. Although this difference is a result of the study's retrospective design, our analysis found no significant correlation between age and ED visits. On the other hand, its strength lies in the ease of patient standardization as it is the only comprehensive ED serving a population of over 60,000 people. Our study represents a pioneering exploration of this topic.

Conclusion

In conclusion, our findings highlight the potential benefits of integrating PT modalities into the comprehensive management of chronic LBP. This not only contributes to improved patient care but is also consistent with the broader goal of reducing the burden of ED. We advocate for further multicenter and prospective studies to validate and extend these findings, offering a more comprehensive understanding of the role of PT in improving the management of chronic LBP and healthcare resource allocation.

Ethics

Ethics Committee Approval: This study was conducted in accordance with the Declaration of Helsinki and was approved by the Local Ethics Committee of Necmettin Erbakan University (decision number: 2023/4514, date: 15.09.2023).

Informed Consent: Retrospective study.

Authorship Contributions

Surgical and Medical Practices: E.A.T., A.Ç., Concept: E.A.T., A.Ç., T.S.M., Design: E.A.T., A.Ç., T.S.M., Data Collection or Processing: E.A.T., A.Ç., Analysis or Interpretation: E.A.T., A.Ç., T.S.M., Literature Search: E.A.T., A.Ç., T.S.M., Writing: E.A.T.

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Greater Occipital Nerve Blockade in the Treatment of Tension-type Headaches in the Emergency Department

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Abstract

Aim: This study aimed to tension-type headache (TTH) investigate the efficacy of greater occipital nerve (GON) blockade performed with dexketoprofen under ultrasonography in patients presenting to the emergency department.

Materials and Methods: This prospective, randomized, controlled study was conducted with patients who presented to the emergency department with TTH. The treatment was planned as 50 mg of intravenous (IV) dexketoprofen over 5 min for Group 1 and IV dexketoprofen followed by ultrasonography-guided GON blockade with 0.5% bupivacaine for Group 2. The patients' demographic characteristics and pain levels according to the 10-cm Visual Analog Scale were recorded at the time of presentation. The pain scores of the patients were recorded at the 10th, 20th, 30th, 60th, and 120th minutes, and the difference between the 0th and 120th minutes was calculated as the delta value.

Results: Of the 159 patients included in the study. There was a decrease in the pain scores at the 10th minute in both groups with treatment, and the greatest decrease occurred in Group 2 at the 20th minute. The delta visual analog scale score was found to be 4.71 in Group 1 and 7.11 in Group 2, and it was observed that GON blockade therapy together with IV dexketoprofen reduced the severity of pain more rapidly and effectively than IV dexketoprofen alone.

Conclusion: When managing acute pain attacks in patients presenting to the emergency department with TTH, the combined use of IV non-steroidal anti-inflammatory drugs with a GON block increases treatment outcomes, reduces treatment duration, and enhances the efficacy of analgesics compared with their use alone.

Keywords: Tension-type headache, treatment, non-steroidal anti-inflammatory drugs, greater occipital nerve blockade

Introduction

Tension-type headache (TTH) is the most common primary cause of headaches, with a high prevalence and significant socioeconomic impact (1). Despite its prevalence and impact on quality of life, there is a lack of comprehensive knowledge on the underlying causes and viable treatment options for TTH (2,3). The triggering effect of psychological stress in the pathophysiology of TTH continues to be valid as a universally acknowledged mechanism (4,5). While the diagnosis is made according to the current clinical situation and the International Headache Criteria, the primary focus of the evaluation of patients with TTH is the exclusion of secondary fatal causes (6). The headache is bilateral and characterized by mild to severe intensity. It may create a sensation of tightness, resembling a band around the head. There are no accompanying neurological signs.

Treatment is tailored based on whether TTH is acute or chronic. Patients seek emergency treatment when their headache intensifies or they are unable to find a solution. Treatment for acute symptoms might vary from non-pharmacological methods to the use of both single and combined analgesic drugs. While pharmaceutical treatment methods such as non-steroidal anti-inflammatory drugs (NSAIDs), adequate sleep, proper posture, and massage techniques are often preferred methods that can alleviate patients' pain, excessive medication use should be

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prevented. However, despite accompanying comorbidities, peripheral nerve procedures, such as nerve blockade and stimulation, can be favored (7). In particular, greater occipital nerve (GON) blockade is a reliable and well-tolerated method for relieving acute and short-term headaches (8,9).

GON blockade is effective in the transmission of sensory information to the nucleus caudalis and in the sensory innervation of the occipital region skin. It also traverses through the layers of the neck muscles, such as the semispinalis capitis and trapezius. Research has demonstrated that GON blockade, which is applied based on mechanical pain sensitivity in the head and neck muscles, is the most prominent finding in TTH and has a pain-reducing effect (7,10,11). The current study investigated the efficacy of GON blockade performed using dexketoprofen under ultrasonography in patients admitted to the emergency department.

Materials and Methods

Study Design

The study was designed as a prospective, randomized, controlled study and was conducted with patients who presented to the emergency department of a tertiary hospital due to TTH from March 2022 to August 2022 following the approval of the Atatürk University Faculty of Medicine Clinical Research Local Ethics Committee (date: 27.01.2022, decision number: B.30.2.ATA.0.01.00/98). All individuals provided written informed consent for inclusion before participating in the study.

Participants and Randomization

All patients who presented to the emergency department with headache as the main complaint were evaluated in the triage unit. Excluded from the study were patients aged 18 and >65 years, those whose vital signs were unstable according to their age, those with additional diseases that cause chronic comorbidities (especially those with coagulation disorders, those receiving anticoagulant treatments, those who had undergone posterior fossa surgery, etc.), pregnant women, patients with headaches of any organic cause, those who were allergic to the treatment protocols to be applied, those who did not agree to participate in the study, and those who did not meet the diagnostic criteria for TTH according to the International Headache Criteria-3 (6).

The treatment protocols to be applied to the patients who met the study criteria were numbered as Group 1 and Group 2 by a physician other than the physician who would perform the treatment, and they were placed in a sealed envelope. The treatment protocols to be applied to the patients who met the study criteria were numbered as Group 1 and Group 2 by a physician other than the one who would perform the treatment. The protocols were then placed in a sealed envelope. The treatment protocol involved the intravenous (IV) administration of 50 mg of dexketoprofen in 100 mL of 0.9% NaCl over 5 min for Group 1 and the IV administration of 50 mg of dexketoprofen in 100 ml of 0.9% NaCl over 5 min, followed by the bilateral administration of 2 mL of bupivacaine at a concentration of 0.5% under ultrasonography guidance. To eliminate gender differences between the groups, 10 envelopes were prepared and labeled as M1, F1, M2, F2, etc. before being placed in boxes. If the envelopes in the boxes ran out, equivalent quantities were added.

GON Block

Patients who agreed to participate in the study and undergo the procedure were placed in a sitting position under standard monitoring (blood pressure, arterial rhythm, and pulse oximetry). The procedure was performed under ultrasonography, under sterile conditions, and using an 8-16-mHz probe. To determine the localization of the occipital nerve, the occipital artery was sonographically detected one-third medial to the distance between the mastoid process and protuberantia occipitalis externa. Following negative pressure aspiration from the medial side of the occipital artery using a 30-G needle, GON blockade was performed by applying 2 mL of bupivacaine at a concentration of 0.5% to both occipital nerves (Figure 1). The hemodynamic data of the patients were monitored for 30 min after the procedure.

Patient Data and Pain Assessment

Upon admission, the patients were asked to complete a study form prepared to determine their demographic characteristics,

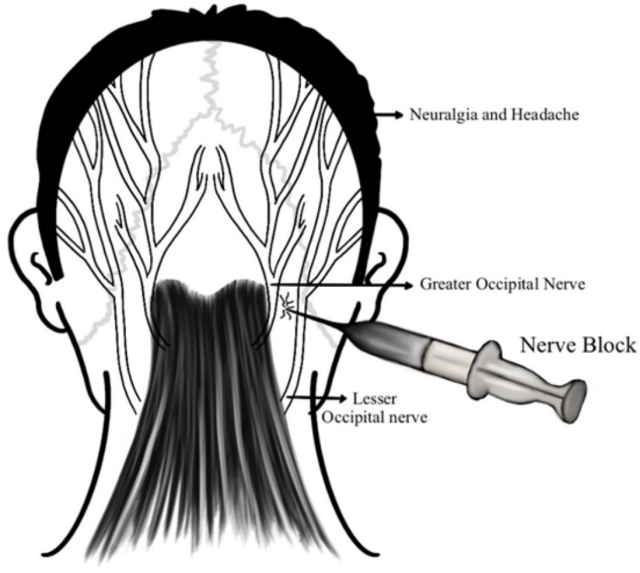

Figure 1. Greater occipital nerve blockade

personal and family history, presentation complaints, pain characteristics, previous use of analgesics, when they used these analgesics, vital signs, physical examination findings, and pain intensity levels according to the visual analog scale (VAS) scored from 0 to 10. The VAS scores of the patients were recorded at the 0th, 10th, 20th, 30th, 60th, and 120th minutes, covering the entire period from their first presentation through 120 min after treatment and/or procedure, regardless of their previous responses. In addition, the delta VAS score was calculated as the difference between the VAS scores evaluated at the 0th and 120th minutes.

Statistical Analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) program (IBM SPSS Statistics for Windows, version 22.0. Armonk, NY: IBM Corp. Data are presented as mean, standard deviation, median, minimum, maximum, percentage, and number. The normality of the distribution of continuous variables was examined using the Shapiro-Wilk test. For comparisons between two independent groups, the independent-samples t-test was used if the normal distribution condition was met, and the Mann-Whitney U test was used otherwise. The comparison of variables between more than two dependent groups was performed using the repeated-measures analysis of variance test in the presence of a normal distribution and the Friedman test otherwise. A p value of 0.05 was considered statistically significant.

Results

Of the 159 patients included in the study, 80 were in Group 1, where IV dexketoprofen was administered, and 79 were in Group 2, where IV dexketoprofen and GON block therapy were administered (Figure 2). There were no statistically significant differences between the two groups in terms of age, gender, or vital signs, with these variables showing a homogeneous distribution (Table 1).

While 47.8% of the patients experienced a headache at least once a month, 6.9% stated that they experienced more than four attacks. At the time of presentation, the patients were asked to describe the type (pressing, throbbing, squeezing, and pulsatile) and location of their headache. The most common type of headache was throbbing (35.2%), followed by squeezing (33.3%). Localization of pain was unilateral in 56% and in the temporal and frontal regions in 29.6%.

Pain characteristics, accompanying symptoms, and family history did not significantly differ between the treatment groups (Table 2).

Table 3 presents the VAS scores of the treatment groups. There was no statistically significant difference between the two groups in terms of the VAS scores evaluated at the time of presentation (0th minute) (p=0.147). However, with treatment, there was a decrease at the 10th minute in both groups, and this was statistically significant (p=0.002). After treatment, the greatest decrease occurred in Group 2 at the 20th minute (Table 3). The delta VAS score was calculated to be 4.71 in Group 1 and 7.11 in Group 2, and it was observed that GON block therapy together with IV dexketoprofen reduced the severity of pain more rapidly and effectively than IV dexketoprofen alone (Figure 3).

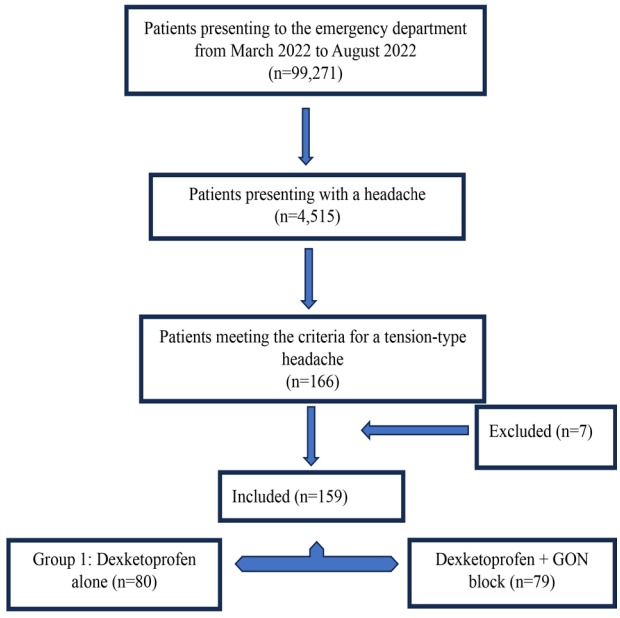

Figure 2. Flowchart of the study
GON: Greater occipital nerve

Table 1. Patients' demographic characteristics and vital signs at the time of presentation

	Group 1 (n=80)	Group 2 (n=79)	p
Gender (female/male)	43/37	40/39	0.694
Age (years)	36.65	37.57	0.654
Systolic blood pressure (mmHg)	120.69	122.47	0.253
Diastolicblood pressure (mmHg)	77.01	77.78	0.523
Pulse (/min)	75.89	76.06	0.897
Respiratory rate (/min)	14.48	14.14	0.250
Body temperature (°C)	36.18	36.14	0.106
Pulse oximetry (%)	96.56	96.89	0.266

Group 1: Dexketoprofen alone, Group 2: Dexketoprofen + greater occipital nerve blockade, min: Minutes

Table 2. Headaches characteristics according to treatment groups			
Headache characteristics	**Group 1 (n=80)**	**Group 2 (n=79)**	**p**
Headache duration before presentation			
Less than 60 minutes	38	33	0.304
More than 60 minutes	42	46	
Localization			
Unilateral	48	41	0.304
Bilateral	32	38	
Associated with exercise	52	46	0.380
Headache at rest	62	58	0.550
Accompanying symptoms			
Nausea	6	6	0.982
Vomiting	2	1	0.567
Photophobia	3	1	0.317
Phonophobia	1	2	0.553
Family history	3	3	0.987
Group 1: Dexketoprofen alone, Group 2: Dexketoprofen + greater occipital nerve blockade			

Table 3. VAS scores of the patients according to treatment groups			
	Mean VAS scores		
Evaluation time	Group 1 (n=80)	Group 2 (n=59)	p value
Minute 0	8.56	8.85	0.147
Minute 10	7.78	6.94	0.002
Minute 20	6.75	4.94	<0.0001
Minute 30	5.64	3.71	<0.0001
Minute 60	4.70	2.62	<0.0001
Minute 120	3.85	1.73	<0.0001
Delta	4.71	7.11	<0.0001
VAS: Visual analog scale			

Discussion

When managing acute pain attacks in patients with TTH, which cause loss of daily activities and work capacity, the use of IV NSAIDs together with a GON block increases the treatment efficacy and shortens the treatment duration compared with their use alone. In addition to increasing patient and physician satisfaction, this treatment is also effective in reducing emergency department crowding, side effects due to medications, and the need for additional medication use.

TTH, a common neurological disorder, affects 26.8% of the general population, with its prevalence reaching its peak in women between 35 and 39 years (12). In particular, the epizootic and chronic subtypes of TTH are more prevalent among women (13). The study found that 52.2% of the participants were female, with a mean age of 37.11 years, and 47.8% had an attack at least once a month. There were also no statistically significant differences between the treatment groups in terms of gender, age, and vital signs of the patients at the time of presentation, indicating a homogeneous distribution, which is consistent with the literature (14,15).

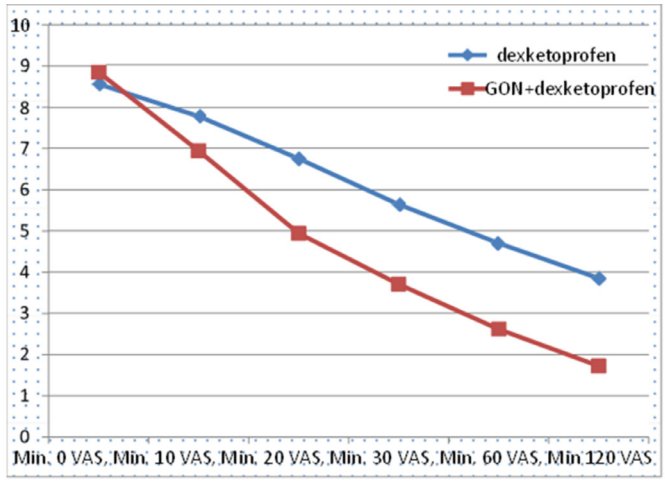

Figure 3. VAS score change graph of the treatment groups
VAS: Visual analog scale, GON: Greater occipital nerve

The diagnosis of primary headaches is based on appropriate clinical evaluation, review of medical history, and assessment of headache onset, duration, and frequency, as well as pain characteristics, accompanying symptoms, aggravating factors, and aggravating factors. Pain that is bilateral, occurs with attacks that are often throbbing or pressing, and lasts between 30 min and 24 h suggests the presence of TTH (13,16). In addition, patients frequently describe the sensation of a rubber band being tightened around the head. Of our patients, 35.2% reported experiencing throbbing pain, 33.3% experienced compressive pain, 56% experienced unilateral pain, and 29.6% experienced pain localized in the temporofrontal region. Pain characteristics were consistent with those reported in the literature, with the exception that some cases were unilateral. Accompanying symptoms are also important to differentiate TTH from migraine. A migraine attack may be accompanied by nausea, vomiting, photophobia, and phonophobia, in addition to an increase in pain (17). However, some case series in the literature have reported a diagnosis of TTH in 53% of patients with nausea (18). In the current study, among the additional symptoms accompanying pain, nausea and vomiting were the most common, occurring in 7.5% of cases. Although 2.5% of the

patients had photophobia, this rate was lower than that of patients with migraine-type headaches.

In TTH, the effect of exercise on pain severity, frequency of headache attacks, headache duration, quality of life, medication use, and psychological symptoms has recently become a controversial issue in the literature (19-21). Various exercise types have been employed for treating these patients, and while it has been reported that aerobic exercises have no effect on reducing the severity of pain, studies have indicated a moderate efficacy of strength exercises in the treatment, albeit with a very low level of evidence (22,23). In the current study, it was determined that the severity of pain increased with exercise in 61.6% of the patients.

TTH is characterized by mild to moderate intensity. Therefore, it responds to lifestyle changes along with pharmacological treatment, such as over-the-counter analgesics (13). In acute pharmacotherapy, it is recommended to use over-the-counter NSAIDs, such as acetaminophen, aspirin, ibuprofen, and naproxen, as well as high-efficacy prescription drugs, including ketoprofen and diclofenac (24). However, because NSAIDs can inhibit the cyclooxygenase pathway, have gastric, hepatic, and renal side effects, and cause increased blood pressure and risk of bleeding, the treatment should be tailored to each individual patient. The majority of studies in the literature focus on migraine headaches, with particular emphasis on the use of acetaminophen and NSAIDs (25-27). The use of NSAIDs is also recommended in the acute treatment of TTH. In a study conducted by Moore et al. (28), the use of 1,000 mg of paracetamol, 400 mg of ibuprofen, and 25 mg of ketoprofen was shown to be more effective than placebo. In addition, in previous studies, dexketoprofen was found to be an effective treatment during acute pain attacks (29,30). However, in our study, we administered a GON block in addition to IV dexketoprofen and observed a more rapid decrease in pain as assessed by VAS.

GON blockade has been previously used for treating various headache types, especially migraine, and a decrease in pain intensity, attack frequency, and analgesic use frequency has been observed (31,32). GON blockade has also been used in TTH and found to be effective in reducing pain severity (7,33). In our study, we found that GON blockade combined with IV dexketoprofen treatment resulted in a decrease in 20th-minute and 120th-minute delta VAS scores compared with the use of IV dexketoprofen alone. The higher decrease indicated by the delta VAS score in cases in which GON blockade was used is an indication of the efficacy of this treatment. The results obtained from the current study align with those reported by studies conducted to date and suggest that GON blockade should be considered a viable therapy option for TTH.

Study Limitations

The most important limitation of our study is that because GON blockade is not included as a sole treatment option in the treatment guidelines, IV dexketoprofen was administered to patients in both treatment groups in line with ethical principles. Therefore, the therapeutic efficacy of GON blockade alone could not be evaluated. The study being conducted in an emergency department and the limited patient follow-up also posed limitations in evaluating the long-term effects of GON blockade. Lastly, the exclusion of individuals with chronic diseases resulted in the study being conducted with data obtained from some patients.

Conclusion

In this study, it was observed that the use of GON blockade together with IV analgesics for treating patients presenting to the emergency department with TTH led to a faster reduction in pain and increased the efficacy of analgesics. It is considered that this combined treatment would also contribute to a decrease in overcrowding by shortening the follow-up period of patients in the emergency department and result in an increase in patient satisfaction.

Ethics

Ethics Committee Approval: The study was approved by the Atatürk University Faculty of Medicine Clinical Research Local Ethics Committee (date: 27.01.2022, decision number: B.30.2.ATA.0.01.00/98).

Informed Consent: Consent form was filled out by all participants.

Authorship Contributions

Surgical and Medical Practices: E.Y.Ç., M.Ç., Concept: E.Y.Ç., Ö.B., Z.Ç., Design: E.Y.Ç., Z.Ç., Data Collection or Processing: E.Y.Ç., M.Ç., Analysis or Interpretation: E.Y.Ç., M.Ç., Literature Search: M.Ç., Ö.B., Writing: E.Y.Ç., Ö.B.

Conflict of Interest: No conflict of interest was declared by the authors.

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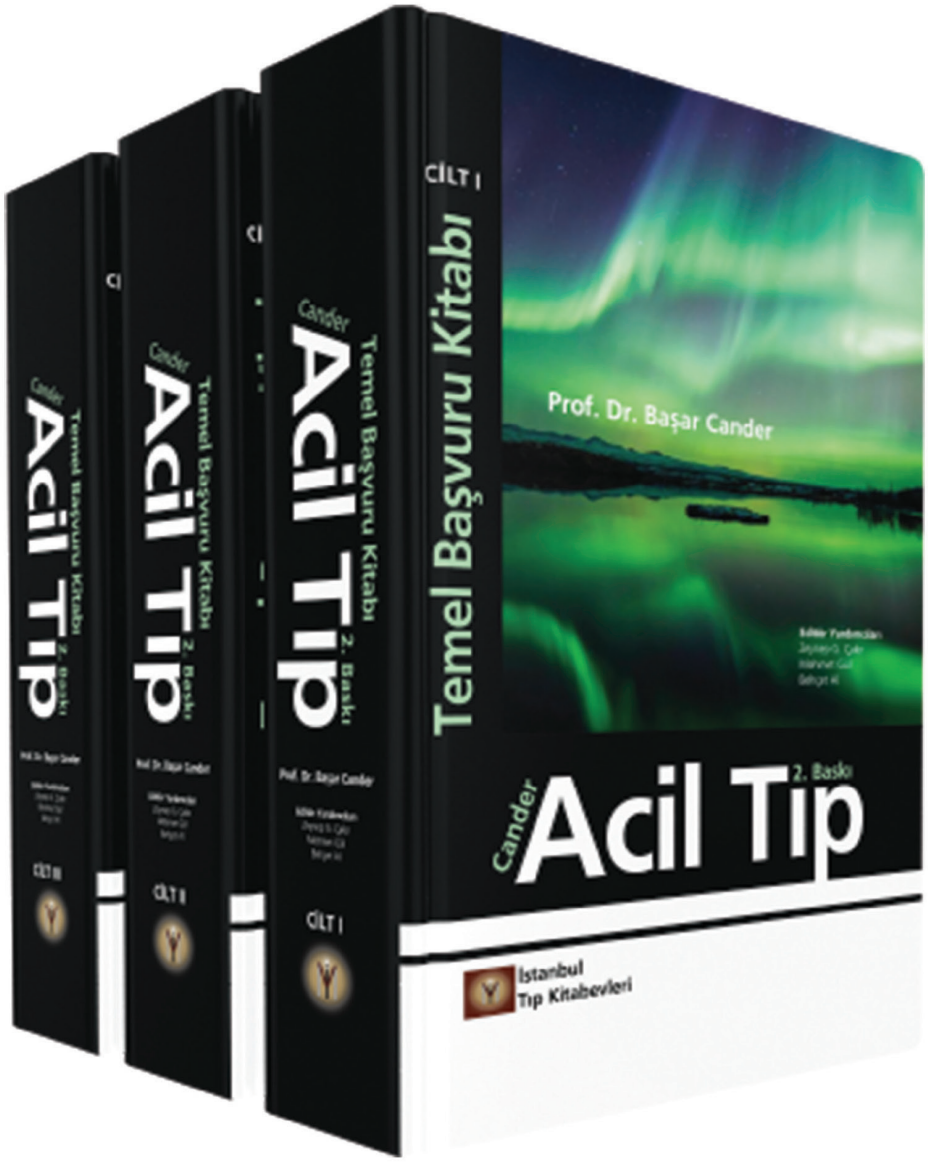

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