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ORIGINAL ARTICLE / ÖZGÜN ARAŞTIRMA MAKALESİ

The Role of Diastolic Dysfunction in the Diagnosis and Treatment of Shock: The Rapid Ultrasound for Shock and Hypotension Protocol with a Diastolic Parameter

Şok Tanı ve Tedavisinde Diyastolik Disfonksiyonun Rolü: Diyastolik Yetmezlik Parametresiyle Birlikte Şok ve Hipotansiyon İçin Hızlı Ultrason Protokolü

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ABSTRACT

Aim: Numerous bedside ultrasound protocols have been developed for the evaluation of critically ill patients with bedside ultrasound. The most widely known of these protocols is the "Rapid Ultrasound for Shock and Hypotension (RUSH)'' protocol. Diastolic dysfunction is the cause of nearly half of left ventricular dysfunctions, but no ultrasound protocol includes diastolic dysfunction. The aim of this study is to evaluate the contribution of the addition of diastolic assessment to the RUSH protocol to the diagnosis and treatment of critically ill patients.

Material and Methods: This prospective, observational study was conducted in a tertiary training and research hospital emergency medicine clinic critical care area for 1 year. Non-traumatic non-pregnant adult patients with systolic blood pressure below 90 mmHg or shock index >1 with signs of circulatory disorder were included in the study. Complaints, clinical findings, and vital signs of all patients included in the study were recorded. With the primary evaluation of the patients, the RUSH protocol was applied, and the findings were recorded. All clinical, laboratory, imaging, and consultation procedures of the patients, as well as the type of shock and its treatment were planned. After the diagnosis of the patients, a second cardiac ultrasound was performed maximum 2 hours later, and diastolic parameters were evaluated and recorded. Whether there was a difference between the diagnoses and treatments of the patients before and after the diastolic parameters were measured, was compared with McNemar and paired T test.

Results: A total of 69 patients with a mean age of 67 ± 13 years were included in the study, 54% of whom were females. Before the diastolic parameters of the patients were evaluated, distributive shock was detected in 20.3%, hypovolemic shock in 18.8%, obstructive-type shock in 8.7% and mixed type shock in 40.6% of the patients and their treatment was arranged accordingly. After evaluating the diastolic dysfunction parameters, distributive shock was found in 15.9% of the patients, hypovolemic shock in 18.8%, obstructive-type shock in 5.7% and mixed type shock in 47.8%. However, this change in diagnoses was not statistically significant (p=0.135). On the other hand, the treatment plans were changed in a total of 13 patients by re-adjusting the volume status due to the determination of the diastolic parameter in those patients, and the change was statistically significant (p<0.001).

Conclusion: Evaluation of the diastolic parameters may not be necessary in determining the shock type in patients with shock. However, the evaluation of the diastolic parameters is effective in adjusting the treatment and volume status of critically ill patients and may need to be evaluated as soon as possible.

Keywords: Emergency medicine, echocardiography, heart failure, bedside ultrasound, critical care

ÖZ

Amaç: Kritik hastaların yatakbaşı ultrasonla değerlendirilmesi için çok sayıda yatakbaşı ultrason protokolü geliştirilmiştir. Bu protokollerden en yaygın bilineni "Şok ve Hipotansiyon için Hızlı Ultrason protokolü: "Rapid Ultrasound for Shock and Hypotension'' (RUSH) protokolüdür. Sol ventrikül disfonksiyonlarının yarıya yakın nedenini diyastolik disfonksiyon içerir ve hiçbir ultrason protokolü diyastolik disfonksiyon yer almamaktadır. Bu çalışmanın amacı RUSH protokolüne diyastolik değerlendirmenin eklenmesinin kritik hastaların tanı ve tedavilerine katkılarını belirlemektir.

Gereç ve Yöntemler: Prospektif gözlemsel olarak planlanan bu çalışma 1 yıl boyunca üçüncü basamak bir eğitim araştırma hastanesi acil tıp kliniği kritik bakım alanında yürütülmüştür. Çalışmaya dolaşım bozukluğu bulguları olan, sistolik kan basıncı 90 mmHg altında veya şok indeksi >1 olan, nontravmatik, gebe olmayan erişkin hastalar dahil edildi. Çalışmaya alınan bütün hastaların şikayetleri, klinik bulguları, vital bulguları kaydedildi. Hastaların primer değerlendirilmesiyle beraber RUSH protokolü uygulandı ve bulguları kaydedildi. Hastaların tüm klinik, laboratuvar, görüntüleme ve konsültasyon işlemleri ile şok tipi ve şok tedavisi planlandı. Hastaların tanı almasını takiben maksimum 2 saat sonra ikinci defa kardiyak ultrason yapılarak diyastolik parametreler değerlendirildi ve kaydedildi. Hastaların diyastolik parametreler bilinmeden önce ve sonraki tanıları ve tedavileri arasında fark olup olmadığı McNemar ve Eşleştirilmiş T testi ile karşılaştırıldı.

Bulgular: Çalışmaya yaş ortalaması 67±13 olan ve %54'ü kadın olan toplam 69 hasta dahil edildi. Hastaların diyastolik parametreleri değerlendirilmeden önce %20.3'ünde distribütif tip şok, %18.8'inde hipovolemik şok, %8.7'sinde obstrüktif tip şok ve %40.6'sında da miks tip şok tespit edilerek bu yönde tedavileri düzenlendi. Diyastolik yetmezlik parametreleri değerlendirildikten sonra hastaların %15.9'unda distribütif tip şok %18.8'inde hipovolemik şok, %5.7'sinde obstrüktif tip şok ve %47.8'inde de miks tip şok tespit edildi ancak tanılarda meydana gelen bu değişiklik istatistiksel olarak anlamlı değildi (p=0.135). Tedaviler ise ağırlıklı olarak hastalarda diyastolik kusurun tespit edilmesine bağlı volüm durumunun yeniden ayarlanması şeklinde değişmiş olup, toplam 13 hastanın tedavisinde değişiklik oldu ve bu değişiklik istatistiksel olarak anlamlı idi (p<0.001).

Sonuç: Hastalarda şok tipinin belirlenmesinde diyastolik parametrenin değerlendirilmesi gerekli olmayabilir. Ancak kritik hastaların tedavi ve volüm durumlarının ayarlanmasında diyastolik parametrenin değerlendirilmesi etkindir ve en kısa zamanda değerlendirilmesi gerekli olabilir.

Anahtar Kelimeler: Acil tıp, ekokardiyografi, kalp yetmezliği, yatakbaşı ultrason, kritik hasta bakımı

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Introduction

Several bedside ultrasound protocols have been developed for the diagnosis and management of treatment of patients in shock, including focused assessment with transthoracic echocardiography (1), bedside limited echocardiography by emergency physicians (2), focused echocardiographic evaluation in life support (3), and rapid ultrasound for shock and hypotension (RUSH) (4). The best known and most widely employed of these protocols is RUSH. This protocol contains three main examination components for explaining the cause of hypotension in critical patients, known as "the tank", "the pump", and "the pipes". "Tank" represents volume status and involves evaluation of the presence of fluid in the abdominal and thoracic compartment and inferior vena cava (IVC) with ultrasound. "Pump" involves evaluation of the heart that is responsible for the pump function, while "pipes" involves evaluation of the aorta and femoral veins, the main channels through which fluid is transported. Evaluation of left ventricular systolic function involves assessment of the chambers of the heart and pericardial field. The aim of this evaluation is the rapid detection of major pathologies capable of causing hypotension and shock, such as left ventricular failure, pulmonary embolism, and tamponade (5). The evaluation of parameters capable of causing hypotension by impairing perfusion, such as severe valvular pathologies and severe diastolic dysfunction, by non-cardiology branches is still at the research level (6) and is not included in cardiac evaluation using the RUSH protocol.

Detailed evaluation of pathologies capable of causing cardiac-related hypotension and shock involves a broad spectrum (7). Several pathologies not evaluated in the classic RUSH protocol can give rise to hypotension, such as myocardial infarction, free wall rupture, severe valve failure, papillary muscle rupture, and left ventricular diastolic dysfunction. Acute decompensated heart failure, the most common cardiac cause of shock, is most commonly due to LV systolic or diastolic dysfunction, with or without additional cardiac pathology, such as coronary artery disease or valve abnormalities (8). Approximately 50% of all heart failures are known to be diastolic heart failure (9). As in systolic heart failure, causes such as irregular use of heart failure medicine, hypertensive episodes, and infections may cause decompensation in diastolic heart failures, leading to perfusion dysfunction and hypotension (8). However, while left ventricular systolic failure is assessed during cardiac evaluation in the RUSH protocol, preserved ejection fraction heart failure is not evaluated. This also suggests that at least 50% of patients in shock or with hypotension due to acute heart failure may be overlooked. To the best of our knowledge no study to date has investigated whether adding the parameter of diastolic dysfunction to the RUSH protocol will contribute to the diagnosis and treatment of hypotensive patients.

The purpose of this study was to evaluate whether the addition of the diastolic dysfunction parameter to the RUSH protocol will contribute to the diagnosis and treatment of hypotensive patients.

Material and Methods

Study design and setting

This interventional study was performed during daily working hours over a one-year period in the emergency medicine clinics' critical care area of an urban hospital with residency training receiving 200,000 patients a year. The critical care area where the study was conducted was located within the emergency department, with a bed capacity sufficient to permit vital monitoring of 16 patients, with eight mechanical ventilators and two ultrasound devices. Critical patients with vital instability presenting to the emergency department for any reason are treated in this area.

Local ethical committee approval (decision no. 2019-GOKAE-0051) was received before the study commenced. Each patient enrolled in the study, or a relative thereof, was informed about the study in detail, and written consent to participate was obtained.

Study Population

In accordance with the definition of shock (10), patients with clinical signs of circulatory disorder and systolic blood pressure <90 mmHg and/or a shock index >1 were prospectively enrolled in the study. Patients aged under 18, pregnant women, patients with trauma, patients referred from another hospital and started on treatment with a preliminary or definite diagnosis, or with pleural effusion or acid in the abdomen associated with known chronic disease were excluded.

Study protocol

Convenience sampling was used. The age, sex, vital findings, presenting complaint and Glasgow Coma Scale score of patients consenting to take part in the study were recorded. Bedside ultrasound was performed concomitantly with primary treatments. The RUSH protocol used to determine the etiology in hypotensive patients was applied in all cases. The bedside ultrasound findings were shared with the physician responsible for care and added to the patients' hospital files. Patients' clinical findings, ultrasound findings, additional test results, and consultation results were combined for diagnosis, and emergency treatment was initiated in the light of those data. Patients who completed their emergency procedures then underwent a second bedside ultrasound in no more than two hours and diastolic pattern measurements were taken. These findings were also shared with the physician responsible for care to follow for changes in the patient's diagnosis and treatment. Patients' primary diagnoses, treatments, and consultation requirements were recorded before and after diastolic dysfunction measurements. Whether knowledge of the diastolic dysfunction pattern would create a significant difference in terms of diagnosis, treatment, and emergency consultation requirements was evaluated by means of statistical analysis.

Bedside ultrasonographic measurements

Sonographic evaluation was performed by a single physician in our study team, who was not the patient's primary physician, in accordance with the RUSH protocol. Bedside ultrasound was performed by a single emergency medicine specialist with eight years' experience of RUSH protocol measurements and with five years' experience as an instructor in the Emergency Medicine Association of Turkey Ultrasound Study Group. For diastolic failure measurements, the same emergency medicine specialist received 2-h theoretical training and 8-h practical instruction involving 20 patients from a specialist cardiologist who had completed formal training. Cardiac measurements were performed with a GE Logiq A5 Ultrasound Machine 3.5-5 MHz sector probe, abdominal evaluations using a Mindray M5 Ultrasound Machine 3.5-5 convex probe, and vascular and pulmonary evaluation with a 7.5 MHz linear probe.

In line with the general consensus in the RUSH protocol (4), cardiac, abdominal cavity (Morison's pouch, the splenorenal area, and pelvic area), aorta, IVC and jugular vein and lower extremities deep veins measurement was performed, together with evaluation of the pulmonary and pleural cavities.

Diastolic failure measurements were performed using mitral valve flow velocity and the anterior mitral annulus in line with European Cardiology Society recommendations (11). Grade 1 diastolic dysfunction was defined as an early diastolic phase flow (E) / atrial contraction phase flow (A) ratio < 1 in which E amplitude decreased and A amplitude increased, characterized by prolongation of isovolumetric relaxation time (IVRT) and deceleration time (DT), known as relaxation impairment. Grade 2 diastolic dysfunction was defined using the characteristics of decreased DT and renormalized trans mitral flow known as a pseudo normal pattern. Grade 3 diastolic dysfunction was defined through the characteristics of E/A>2, with an increased E wavelength, a decreased A wavelength, and shortened IVRT and DT, known as the restrictive pattern (11).

Outcome measures

The primary outcome of the study was the diagnoses responsible for shock. The secondary outcome was the therapeutic protocol applied, and the tertiary outcome was patients' consultation requirements. The study then investigated whether the addition of the diastolic dysfunction parameter to the RUSH protocol applied to patients would produce any change in patients' diagnoses, treatments, and consultation requirements.

Statistical analysis

Descriptive statistics were expressed as frequency, percentage, mean and standard deviation. Categorical variables were expressed as numbers and percentages, while numerical variables were expressed as mean plus standard deviation. Continuous variables were tested for normal distribution using histogram, kurtosis, and skewness values, as well as the Shapiro-Wilks test. The McNemar test was applied in the comparison of categorical variables in dependent groups. The paired T test was used to compare continuous variables between dependent groups. A p value <0.05 was considered statistically significant. All statistical analyses were conducted on SPSS 24.0 software, and all calculations were made at a 95% confidence interval.

Results

One hundred ninety-eight patients meeting the inclusion criteria during daily working hours over the one-year study period and consenting to take part were enrolled in the study. Twenty-two of these patients were excluded due to trauma-related circulatory disorder, 47 due to having been previously diagnosed or treated at another center, 31 due to free fluid in the abdominal, pleural, or pericardial areas resulting from known chronic diseases, and 29 due to having inappropriate echogenicity for detailed echocardiographic measurement. Sixty-nine patients, with a mean age 67 ± 13 years, of whom 54% was women, were finally enrolled. A workflow chart is shown in Figure 1. In the light of the clinical findings, laboratory results, radiological imaging, the RUSH protocol, and consultation procedures, a manifestation of distributive shock was determined in 20% of the patients included, hypovolemic shock in 19%, cardiogenic shock in 12%, obstructive shock in 9%, and mixed type shock in 40%. Patients' general characteristics, vital findings at presentation, final diagnoses following the RUSH protocol and radiological imaging are shown in Table 1.

At least Grade 1 diastolic dysfunction was determined in 24 patients. Severe diastolic dysfunction was present in 13 of these. Eight of the patients with severe diastolic dysfunction were in cardiogenic type shock, two were in obstructive shock due to tamponade / pericarditis, and three were in distributive shock. In addition, the severe diastolic dysfunction manifestation in eight patients with cardiogenic shock caused no change in shock classifications but changed to mixed type in the other three patients in distributive shock and two patients in obstructive shock. Cases in which first shock classifications agreed with the clinical manifestations after completion of the classic RUSH protocol and emergency tests, and patients' shock classifications after the addition of the diastolic dysfunction parameter to the RUSH protocol are shown in Table 2. McNemar Bowker analysis showed that this change occurring in the shock classification through a knowledge of the patient's diastolic parameters was not statistically significant (p= 0.135).

The patients in the study population were started on emergency treatment in the knowledge of the RUSH protocol results in the context of emergency diagnosis and treatment, but before diastolic measurements were performed. Varying degrees of diastolic dysfunction were determined in 24 patients following evaluation of diastolic parameters. Whether this diastolic dysfunction would cause a modification of the patients' treatment was then investigated. Eight patients with cardiogenic shock only and two with obstructive shock were already receiving treatment for heart failure, and the knowledge of diastolic dysfunction

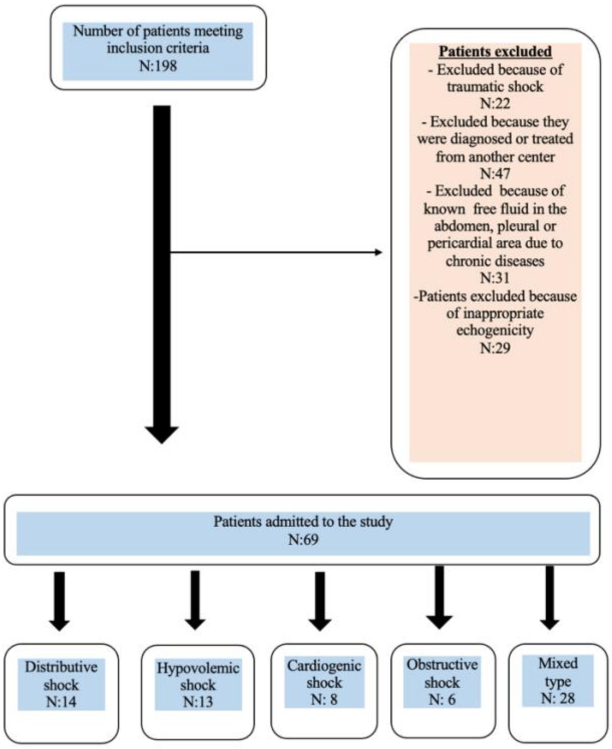

Figure 1: Work Flow Chart

in these caused no change in their treatment. No diastolic dysfunction was observed in any patient in the hypovolemic shock group. However, treatment was modified in nine patients with mixed type shock and four with distributive shock. This modification took the form of slowing fluid replacement and transitioning to controlled fluid replacement in four patients with distributive shock, because moderate-severe diastolic dysfunction was detected in these patients. Therefore, fluid replacement for hypotension was slowed and controlled. In addition, the fluid given due to distributive shock in five of nine patients with mixed type shock was slowed down due to the addition of diastolic dysfunction, and diuretic therapy was added to four of them whose volume status was evaluated as normal-slightly high due to the addition of diastolic dysfunction. After the modifications, the patients' vital signs improved clinically, and no worsening was observed in relation to the treatment arranged in the clinic of any patient. This change in the treatment regimens of 13 patients was statistically significant according to the McNemar test (p< 0.001).

General characteristics and vital signs	**Values at the time of admission**
No.	69
Age years (mean ± SD)	67 ± 13
Female n (%)	37 (54 %)
MAP (mmHg) (mean ± SD)	61 ± 10
Pulse rate (/minute) (mean ± SD)	119 ± 18
Respiratory rate (/minute) (mean ± SD)	28 ± 6
Medical history	
Congestive Heart Failure n (%)	17 (24 %)
Diabetes Mellitus n (%)	30 (43 %)
Chronic Renal Failure n (%)	9 (12 %)
Hypertension	38 (55 %)
Chronic obstructive pulmonary disease n (%)	19 (27 %)
Cirrhosis	5 (7 %)
End-Diagnosis	
Pneumosepsis	15 (22 %)
Urosepsis	7 (10 %)
Pancreatitis	3 (4 %)
Cholecystitis-cholangiosepsis	5 (7 %)
Peritonitis	2 (2 %)
Gastroenteritis, nausea, vomiting and dehydration due to malnutrition and diuretic overdose	15 (22 %)
Upper and lower gastrointestinal bleeding	7 (10 %)
Ruptured aortic aneurysm and aortoenteric fistula	3 (4 %)
Third space fluid loss due to intestinal obstruction, hypoproteinemia, and cirrhosis	6 (8 %)
Anaphylaxis	1 (1 %)
Pulmonary embolism, severe pulmonary hypertension severe valve stenosis	9 (13 %)
Acute heart failure (exacerbation of congestive heart failure or acute coronary syndrome)	16 (23 %)
Tachyarrhythmia-bradyarrhythmia	6 (8 %)
Pericardial tamponade and pericarditis	2 (2 %)
Obstruction due to massive pleural effusion and tension pneumothorax	3 (4 %)

Table 1. Demographic characteristics and vital signs of subjects

Patients' diastolic dysfunction evaluations and treatment modifications are shown in Table 3.

Discussion

Sixty-nine patients with circulatory disorder were included in this study, and the RUSH protocol, one of the most widely employed protocols, was employed as a bedside ultrasound protocol at diagnosis. The main components of the RUSH protocol in cardiac evaluation involve assessment of the cardiac chambers, the pericardial area, and left ventricular function (4). The principal aim with these parameters is to

Shock Classification	Pre-diastolic assessment	Post-diastolic assessment	P
Distributive shock	14 (20.3%)	11 (15.9%)	
Hypovolemic shock	13 (18.8%)	13 (18.8%)	
Cardiogenic shock	8 (11.6%)	8 (11.6%)	0.135
Obstructive shock	6 (8.7%)	4 (5.7%)	
Mixed type	28 (40.6%)	33 (47.8%)	
Total	69 (100%)	69 (100%)	

Table 2. Shock classifications of subjects before and after evaluation of diastolic parameter

identify the main causes of shock, such as pulmonary embolism causing dilatation in the right cardiac chambers, tamponade, an obstructive pathology, and severe left-side heart failure. However, it is important to remember that approximately half of heart failures consist of diastolic dysfunctions (9), and none of the existing bedside ultrasound protocols assesses the diastolic dysfunction parameters (12-16). To the best of our knowledge, this study is the first to include this parameter in the evaluation of critical patients with emergency ultrasound. The findings revealed that knowing the diastolic parameter in shocked patients caused no significant change in shock classification. However, knowledge of that parameter caused a statistically significant change in patients' treatment, particularly in terms of volume status adjustment. This shows that the diastolic parameter may not be essential in determining the pathology responsible for patients' critical status and their chock classification, but evaluating that parameter in the shortest possible time is essential for volume status adjustment in critical patients. The most common type of shock in our study populations was mixed type, at 40%, followed by distributive shock at 20%. Distributive shock was present in almost all the mixed type patients and was combined with hypovolemic or cardiogenic shock. Thomas et al.'s review of studies published over an approximately 30-year period reported that distributive shocks constituted 59-66% of all shock types, without mixed type being included in the data (17). Among the other types of shock in the present study, hypovolemic shock was present at a rate of approximately 19%, cardiogenic shock at 12%, and obstructive shock at approximately 9%. Thomas et al. reported hypovolemic shock at 16-27%, cardiogenic shock at 13-16%, and obstructive shock at 1-2%. The data from the present study are compatible with the statistical findings reported by Thomas et al. and thus show that our study population reflects the general population. We think that the minor differences between our studies may derive from mixed type shock being included in our classification and to our exclusion of trauma patients. Cardiogenic shock patients constituted 12% of our study population (Table 2), and severe diastolic failure was determined in all these at diastolic dysfunction evaluation (Table 3). However, the diastolic dysfunction determined in these patients caused no change in either their shock classifications or treatment. This may be explained as follows: impairment in cardiac functions is known to begin with diastolic dysfunction, and this is already present in every patient with severe systolic dysfunction (18-20). Therefore, every patient diagnosed with cardiogenic shock due to severe systolic dysfunction receives the requisite diuretic or positive inotropic therapy for severe heart failure treatment. It was therefore not surprising that a diastolic dysfunction identified in these patients caused no change in their diagnosis or treatment. This also suggests that diastolic dysfunction evaluation in patients in cardiogenic shock may be unnecessary.

Shock Classification	Pre-diastolic assessment N (%)	Diastolic failure N (%)	Severe Diastolic failure N (%)	Treatment changes N (%)	P
Distributive shock	14 (20.3%)	5 (7.2%)	3 (4.3%)	4 (5.7%)	
Hypovolemic shock	13 (18.8%)	0 (0%)	0 (0%)	0 (0%)	
Cardiogenic shock	8 (11.6%)	8 (11.6%)	8 (11.5%)	0 (0%)	
Obstructive shock	6 (8.7%)	2 (2.8%)	2 (2.8%)	0 (0%)	**<0.001**
Mixed type	28 (40.6%)	9 (13%)	0 (0%)	9 (13%)	
Total	69 (100%)	24 (34.7%)	13 (18.8 %)	13 (18.8%)	

Table 3. Evaluation of the changes in the treatment of subjects because the diastolic failure

Heart failure is a clinical diagnosis, and these patients are primarily diagnosed through clinical evaluation such as the Framingham criteria (21). The underlying cause of clinical heart failure may be systolic dysfunction, diastolic dysfunction, or a valvular pathology. All these causes present with similar clinical manifestations, and it is not possible to identify the underlying cause by clinical means, but is only possible by echocardiographic evaluation. Critical patients first present to the emergency department, and are first evaluated by emergency physicians. Numerous ultrasound protocols have been developed for the evaluation of emergency and critical patients, and almost all include cardiac evaluation (2, 12-13, 22). However, the cardiac evaluations in these protocols have remained superficial, and consist of crude ratios between cardiac chambers, left ventricular systolic function, and tamponade. Although valvular pathologies and diastolic dysfunction parameters are valuable in terms of the ability to account for the existing failure manifestations in these patients, these have not yet been included in any of the protocols. Evaluation of these parameters by emergency physicians requires a certain level of experience and training, and there are studies showing that the diastolic dysfunction parameter can be successfully evaluated by emergency physicians with a short training model (23-24). The addition of the diastolic dysfunction parameter to these protocols may therefore be an easily learned, useful, and effective method in organizing the treatment of critical patients.

Limitations

The principal limitations of this study are its single-center nature and relatively low patient number. In addition, determining the main causes in shocked patients with circulatory impairment may be complicated, particularly in case of progressive shock. The involvement of endocrinological shock in prolonged shock may make it difficult to clearly identify the principal pathology responsible for shock. In addition, acidosis may frequently accompany the clinical manifestation in prolonged shock. Accompanying profound acidosis may suppress cardiac function, thus adding cardiogenic shock to the clinical manifestation (25). The aim in this study was to exclude patients with advanced shock by excluding cases referred from external centers, thus avoiding this and similar confusion.

Conclusion

No statistically significant change in hypotensive patients' shock classifications was observed when evaluation of the diastolic dysfunction parameter was added to the RUSH protocol. However, diastolic dysfunction assessment did result in a significant modification of the treatments of shocked patients. Therefore, although evaluation of diastolic dysfunction may not be essential in determining the causes of shock, it may play an important role in the management of emergency treatments, particularly in the regulation of fluid therapies. Further randomized, and controlled studies with larger patient numbers are now needed to confirm this.

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Author declared that she follow the rules of Research and Publication Ethics.

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