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Accuracy of bedside sonographic measurement of optic nerve sheath diameter for intracranial hypertension diagnosis in the emergency department

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Abstract

Ultrasound measurement of the optic nerve sheath diameter (US ONSD) has been proposed as a method to diagnose elevated intracranial pressure (EICP), but the optimal threshold is unclear. The aim of this study was to assess the accuracy of US ONSD, as compared to head computed tomography (CT), in detecting EICP of both traumatic and non-traumatic origin. We conducted a prospective, cross-sectional, multicenter study. Patients presenting to the emergency department with a suspect of traumatic or non-traumatic brain injury, referred for an urgent head CT, underwent US ONSD measurement. A US ONSD ≥5.5 mm was considered positive. Sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood ratios were calculated for three ONSD cut-offs: 5.5 (primary outcome), 5.0, and 6.0 mm. A receiver operating characteristic (ROC) curve was also generated and the area under the ROC curve calculated. Ninety-nine patients were enrolled. The CT was positive in 15% of cases and the US ONSD was positive in all of these, achieving a sensitivity of 100% [95% confidence interval (CI) 78; 100] and a negative predictive value of 100% (95% CI 79; 100). The CT was negative in 85% of cases, while the US ONSD was positive in 69% of these, achieving a specificity of 19% (95% CI 11; 29) and a positive predictive value of 18% (95% CI 11; 28). The US ONSD, with a 5.5 mm cut-off, might safely be used to rule out EICP in patients with traumatic and non-traumatic brain injury in the ED. In limited-resources contexts, a negative US ONSD could allow emergency physicians to rule out EICP in low-risk patients, deferring the head CT.

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Ethics approval and consent to participate: the study did not require ethical approval because it was a quality improvement project to implement the current recommendations on the use of ultrasound for measuring ONSD in patients with an acute neurological condition and had no contraindications for patients undergoing the diagnostic investigation, as there were no side effects, which made it unnecessary to apply to the ethics committee.

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Introduction

Traumatic and non-traumatic brain injury can result in elevated intracranial pressure (EICP). EICP is a potentially life-threatening condition that can cause cerebral ischemia and brain herniation, leading to permanent neurologic sequelae. Monitoring and normalizing the intra-cranial pressure (ICP) is crucial to reduce secondary neurological injuries and the associated morbidity and mortality.[1,2] EICP is defined as values of 20 mmHg or more measured through to the insertion of a catheter inside the brain.[3] Invasive ICP measurement with external ventricular drains (EVD) and intraparenchymal monitors (IPM) continues to be the reference standard but is associated with increased risk of infection and hemorrhage and cannot be routinely used in the Emergency Department (ED) settings.[4-7] In usual practice, non-invasive diagnostic tests are more frequently used. In the ED, head computed tomography (CT) is the first screening neuroimaging test used to detect EICP, determine its cause, and classify the severity of the brain injury. Head CT shows a good accuracy when compared to invasive measurement of ICP.[8,9] Magnetic resonance is not used as commonly as CT to diagnose EICP due to costs, time required for the execution, and availability in many centers. Ophthalmoscopy was traditionally described as a test to assess patients with suspect of EICP but this skill is being lost over the years in the ED setting. Furthermore, in patients with altered mental status, performing an ophthalmoscopy can be challenging. Moreover, in the COVID-19 pandemic era, close contacts to patients are not recommended. In recent years, ultrasound measurement of the optic nerve sheath diameter (US ONSD) has been proposed as an alternative test for the diagnosis of EICP.[10,11] Each optic nerve is in fact sheathed in meningeal layers, and elevation of subarachnoid pressure can cause ONSD expansion as a result of intra-orbital and intra-cranial subarachnoid space communication. US ONSD can be safely performed at the bedside in a few minutes, requires no radiation exposure and no patient transportation, and is repeatable, safe and cheap. Moreover, low intra-observer and inter-observer variability have been reported in the medical literature.[12] Several studies investigated the optimal US ONSD cut-off to detect EICP, using CT scan as the reference standard. However, these studies were conducted on small samples and in specific population and settings (*e.g.*, intensive care unit).[13-16] Moreover, in many cases, a case-control design was used and a diagnostic cut-off was not pre-specified, and this might have biased the results. Therefore, a specific cut-off for the adult ED population is not established, limiting the use of this test. Nevertheless, several studies and recent meta-analyses suggest that a diameter >5 mm is associated with an ICP >20 mmHg in adults.[17-22] These studies used a low cut-off, probably with the aim of reaching a high sensitivity. The use of a higher cut-off (5.5 mm) might translate in a higher specificity, hopefully with a small loss in sensitivity.

The aim of this study was to assess the diagnostic accuracy of the US ONSD performed at the bedside by trained operators, as compared to head CT, in adult patients presenting to the ED for traumatic or non-traumatic brain injury, in which the attending physician suspected the presence of EICP. We pre-specified a 5.5 mm cut off for the primary analysis, and 5.0 and 6.0 mm for secondary analyses.

Materials and Methods

A prospective, cross-sectional, multicenter study was conducted at the EDs of San Giovanni Battista Hospital, Foligno, Umbria, and Torrette Hospital, Ancona, Marche, in Italy. The former is a community Hospital with about 35,000 ED visits per year and the latter is a large urban teaching hospital with approximately 60,000 ED visits per year.

Patients were enrolled by a group of emergency physicians with a training in emergency ultrasound that performed the US ONSD.

During the study period, any adult patient presenting to the ED for traumatic and non-traumatic brain injury who was referred for an urgent CT scan was potentially eligible for enrolment, after initial assessment and emergency treatment. The patients satisfying the eligibility criteria were then enrolled not consecutively but only when an operator with ultrasound expertise was on shift. Patients enrolled underwent US ONSD within one hour from the execution of the CT. The subjects aged <18, with significant orbital trauma, any condition leading to an increase in the ONSD (history or suspicion of optic neuritis, glaucoma, expansive endo-orbital lesions), or a chronic EICP were excluded from the study.

The following baseline characteristics were collected: age, sex, triage assessment (color coding), Glasgow Coma Scale (GCS) and hemodynamic parameters, CT findings, monocular and binocular ONSD. Data were stored in a confidential encrypted de-identified database.

The US ONSD was performed as described by Soldatos *et al.*:[23] patients were supine with both eyes closed; abundant gel was applied on the eyelid; a linear high-frequency probe (7.5-10 MHz) was used. The US machines used were a Sonosite Micromax in one site and a General Electric Logiq p5 in the other one. After obtaining an axial visualization of the optic nerve, the ONSD was measured 3 mm posterior to the papilla. The measurement was repeated twice and averaged per each eye (Figure 1).

The highest average (right or left) was used. Considering the good inter-rater agreement reported in the literature for this test,[12] the measurements were performed by one operator per patient. Being intracranial hypertension a dynamic condition, the measurement was performed within one hour to the CT execution. The researcher measuring the ONSD was blinded to the CT results but not to the clinical conditions of the patients.

A US ONSD >5.5 mm was considered positive. This cut-off was specified before the execution of the study. The study participants were then referred for head CT as per usual practice, using a General Electric CT 64s or a Philips brilliance 16s. The CT images were reviewed by two radiologists with experience in neuroradiology and in blind to the patients' clinical conditions and the US ONSD results. Criteria for diagnosis of EICP at the CT scan were one or more of the following: effacement of the sulci with evidence of significant edema or abnormal mesencephalic cisterns, mass effect with midline shift of 3 mm or more, signs of brain herniation, obstructive hydrocephalus, collapse of the third ventricle, anomaly of the mesencephalic cistern.

Statistical analysis

Baseline patient characteristics were reported using standard descriptors of central tendency and variability [median and first, third quartiles (Q1, Q3)] for continuous variables and percentages for dichotomous variables. Baseline characteristics of patients with and without EICP at the head CT were compared using a rank-sum

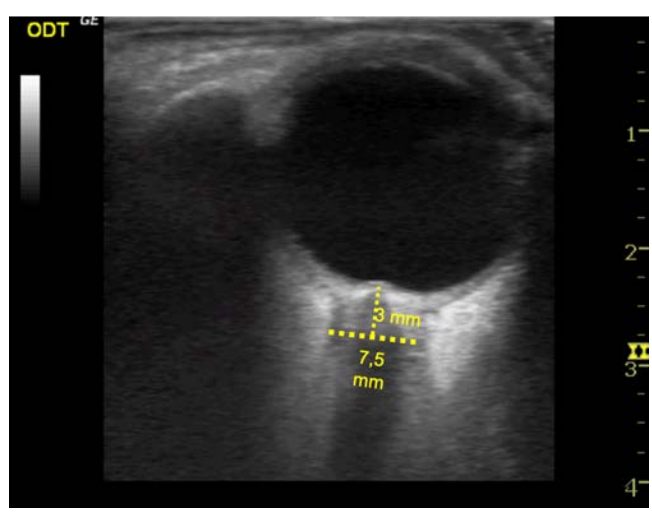

Figure 1. ONSD was measured 3 mm posterior to the papilla using a linear probe transducer A US ONSD >5.5 mm was considered positive.

test and the Fisher's exact test for continuous and categorical variables respectively. Sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood ratios were calculated for three ONSD cut-offs: 5.5 (primary outcome), 5.0, and 6.0 mm. A receiver operating characteristic (ROC) curve was also generated and the area under the ROC curve calculated. We were not expecting to have missing data and decided to perform a complete case analysis. Data were analyzed using STATA/SE V.16 (StataCorp, College Station, TX, USA).

The measurement of the ONSD in trauma patients with suspected EICP is recommended in the Ultrasound-Enhanced ABCDE Assessment promoted by many authors and by the Italian Society of Emergency Medicine (SIMEU).[24] We implemented the use of this technique in the frame of a quality improvement project. Considering this and the fact that the data in the dataset were fully de-identified, no research ethics board approval was required.

Results

One hundred patients were enrolled in this study. In one patient, the ONSD was measured, but she did not receive the CT as she was found to be pregnant. The study flow is reported in Figure 2. Both the index test and the reference standard were performed in the remaining 99 patients. Demographic and clinic characteristics of the population are reported in Table 1. The median (Q1; Q3) age was 66 (46; 78) and 44 (44 %) patients were females. The median (Q1; Q3) GCS was 4 (3; 15) and 15 (15; 15) in patients with and without CT signs of intracranial hypertension, respectively.

The CT was positive in 15 (15%) patients and the US ONSD was positive (≥5.5 mm) in all of these, achieving a sensitivity of 100% (95% CI 78; 100) and a negative predictive value of 100% (95% CI 63; 100). Furthermore, the CT was negative in 84 (85%) patients while US ONSD was positive in 69% of these, achieving a specificity of 19% (95% CI 11; 29) and a positive predictive value of 18% (95% CI 11; 28; Table 2).

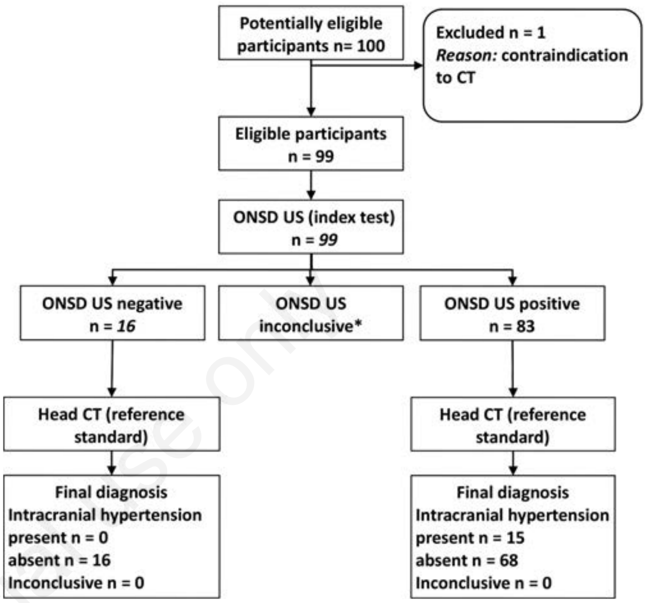

Figure 2. Study flow.

Table 1. Characteristics of the study population.

	All patients	Negative CT	Positive CT	p
	Median (Q1; Q3) or n (%)			
Number of patients	99	84 (84.8)	15 (15.2)	-
Age (years)	66 (46; 78)	61.5 (44.5; 77.5)	71 (58; 85)	0.132
Female sex	44 (44.4)	36 (42.9)	8 (53)	0.575
Systolic blood pressure (mmHg)	137 (125; 160)	136 (125; 155)	140 (120; 177)	0.646
Diastolic blood pressure (mmHg)	78 (70; 87)	77.5 (70; 85)	80 (70; 98)	0.364
Heart rate (bpm)	80 (69; 90)	80 (71; 90)	70 (63; 110)	0.204
Sa02 (%)	98 (96; 99)	98 (96; 99)	97 (96; 98)	0.542
GCS	15 (14; 15)	15 (15; 15)	4 (3; 15)	<0.001
Color code				0.634
Red	42 (42.4)	34 (40.5)	8 (53.3)	
Yellow	34 (34.3)	29 (34.5)	5 (33.3)	
Green	23 (23.2)	21 (25.0)	2 (13.3)	
ONSD (cm)	0.63 (0.57; 0.71)	0.62 (0.57; 0.68)	0.72 (0.64; 0.83)	0.002

CT, computed tomography; Q1, first quartile; Q3, third quartile.

Table 2. Diagnostic accuracy for ONSD ≥0.55.

	CT +	CT -	Tot
US +	15	68	83
US -	0	16	16
Tot	15	84	99

US, ultrasound; CT, computed tomography.

The sensitivity, specificity, positive and negative predictive values, and likelihood ratios for three different ONSD diagnostic cut-offs are reported in Table 3. The area under the ROC curve was 0.75 (95% CI 0.61; 0.88; Figure 3).

Discussion

Our study showed that the US ONSD, using a cut-off of 5.5 mm, had a 100% sensitivity and a 19% specificity to detect EICP, using the head CT as the reference standard. This confirms that this test can safely be used to rule out EICP in patients with traumatic and non-traumatic brain injury in the ED setting.

EICP is one of the main causes of mortality in traumatic and non-traumatic brain injury regardless of the etiology. Its immediate diagnosis and treatment can strongly improve the patients' prognosis. Several methods can be used to identify EICP but, in daily practice, it's mainly diagnosed using head CT scanning due to its availability and cost-effectiveness in emergent situations.

Our results agree with previous studies. We confirmed that US ONSD is a feasible technique that could be easily performed bedside by trained physicians in the emergency setting without interrupting patients' treatment and its very well tolerated by patients.

The ultrasound study of the optic nerve sheath diameter has proven to be easy and quick to acquire by emergency physicians, with a very steep learning curve. It presents few technical difficulties, the main one being the inability to reach one or both eyeballs. This is especially true for patients with severe facial trauma or burns where the anatomy of the orbits and eyeballs is severely compromised or when the eyelids are covered with foreign material such as gauze or foreign bodies in penetrating trauma. Reduced or absent patient cooperation (patients with dementia, intoxicated, with acute traumatic and non-traumatic brain injury) also makes the examination very complicated without adequate sedation.

Limitations have already been partly mentioned above such as an albeit modest intra- and inter-operator variability in measurement readings, inability to establish with certainty the direction of gaze with lowered eyelids by standardizing the readings, technical difficulties related to the blooming effect. The latter ultrasound artifact is determined by an increased echogenicity of structures that are located deeper than structures with high water content such as the eyeball, altering their contours and consequently making the detections less accurate. Some authors suggest using A-mode instead of B-mode which would allow to eliminate the blooming effect. However, the B-mode study is generally simpler to perform, makes it easier to identify the distance at which to take measurements behind the eyeball, and can also be employed on patients with reduced levels of cooperation such as those routinely present in the emergency room.

Low intra-observer and inter-observer variability have already been shown within differences of 0,2-0,3 mm in diameter,[12] therefore we decided to perform the measurements by one operator per patient. Although the learning curve for experienced sonologists may just include a few scans, pitfalls and detection of artefacts could be common during the examination. For this reason, Soroushmehr *et al.* proposed an image processing approach in which the optic nerve sheath diameter was measured automatically, but they found that the average percentage of error between this method and the experts' measurements did not substantially differ from the error between the two experts.[25]

In the past years, many studies explored the diagnostic accuracy of US ONSD for EICP diagnosis. A good sensitivity (100%) with low specificity was shown in different settings and populations, and confirmed in metanalyses, although a specific cut-off was not clear. Robba *et al.*, in 2018,[17] published a metanalysis including studies in which US ONSD measurement was compared with ICP by invasive devices and found a good diagnostic accuracy for US ONSD. Kim et al conducted a metanalysis finding that US ONSD >5.0 mm had a sensitivity of 99% and a specificity of 73% in elevated ICP detection demonstrated by CT, suggesting that it is feasible to use US ONSD for identifying EICP in adult patients.[26] We did not confirm such a high specificity. The specificity estimate in this meta-analysis might be biased by the inclusion of studies with very low samples, very high prevalence of EICP, and/or high percentages of patients with traumatic brain injury.

In our study, the use of a 5.5 mm cut-off allowed us mildly increasing the specificity of the methodic without losing sensitivity. This is an important result for a screening test, that might allow saving the execution of head CT, therefore reducing radiation exposure, processing time, and the use of resources in the ED.

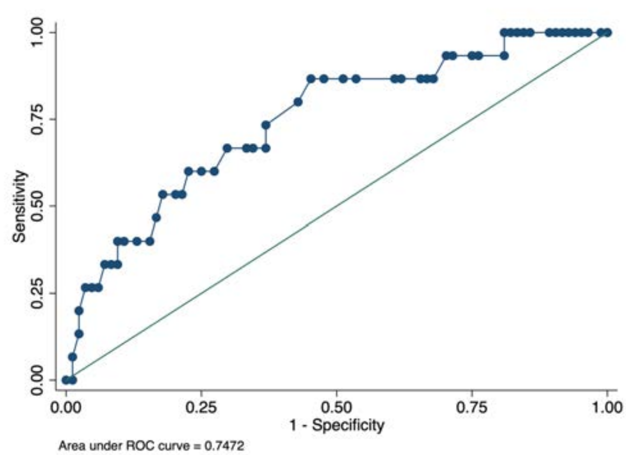

Figure 3. Receiver operating characteristics curve for the ONSD.

Table 3. Diagnostic properties of different US cut-offs, using CT as the reference standard.

Cut-off (mm)	Sn (95% CI)	Sp (95% CI)	PPV (95% CI)	NPV (95% CI)	LR +	LR -
≥5.0	100% (78; 100)	10 % (4; 18)	17% (10; 26)	100% (63; 100)	1.1	0.0
≥5.5	100% (78; 100)	19% (11; 29)	18% (11; 28)	100% (79; 100)	1.2	0.0
≥6.0	87% (60; 98)	38% (28; 49)	20% (11; 32)	94% (80; 99)	1.4	0.4

US, ultrasound; CT, computed tomography; Sn, sensitivity; Sp, specificity; PPV, positive predictive value; NPV, negative predictive value; LR, likelihood ratio.

Strengths

Strengths of our study were the prospective cohort design and the use of a pre-specified cut-off. It's well known that case-control studies, or the use of post-hoc determined cut-offs, are likely to bring to an overestimation of diagnostic accuracy (diagnostic odds ratio increased up to 3 times), while we are confident that the chosen study design produced a trustable estimate of the diagnostic accuracy of the index test. Moreover, the blinding of US operators to the reference standard, and the assessment of the reference standard by a blinded and experienced radiologist strengthens the validity of the results. The generalizability of our results is supported by the fact that the study was conducted in two centers.

Limitations

The "gold" standard for the diagnosis of EICP is the direct intraventricular measurement, which is an invasive procedure, usually reserved to patients requiring an ICP monitoring for traumatic and non-traumatic brain injury or to selected patients with worsening neurological exam and elevated suspect of EICP.[27] Since the use of this method is not routinely justifiable in the ED setting, we chose head CT as the reference standard because in daily practice is accepted not only for the diagnosis of EICP.[28]

Blinding the ultrasound operator to the clinical conditions of the patients would have been very unpractical. This may have introduced some measurement bias. However, we think that this approach reflects real-life conditions, where bedside ultrasound is performed in the ED by physicians directly involved in the care of the patients. The presence of a spectrum effect is possible, and unfortunately our sample size did not allow exploring it in a subgroup analysis, aimed at assessing the diagnostic accuracy of the test in the above-described different populations. We did not explore variations related to BMI, ethnic group, sex, and age. However, Vaiman *et al.* reported mean ONSD variation in different age groups in pediatric population but ONSD in adults did not correlate with age or gender.[29] Lastly, our finding of a 100% sensitivity is weakened by a lower limit of the 95% CI of 78%. Achieving a higher precision, *e.g.*, a lower 95% CI of 90% in our population with a prevalence of EICP of 15% would have required enrolling 475 patients.

Future directions

The evidence produced with this study is not definitive: the high sensitivity of the index test should be further tested in a study in which patients are managed according to the test itself. For example, in a low-resources context and in low-risk patients (GCS 14-15, absence of hemorrhagic risk factors) affected by traumatic and non-traumatic brain injury, the timing for head CT execution could be based on US ONSD measurement: in case of ONSD ≤5.5 mm within 6-8 hours, in case of >5.5 mm within 1 hour. This would not apply to patients with suspected stroke or other indications to perform a head CT as soon as possible. Another possible application would be the use of the US ONSD for the longitudinal follow-up of patients with conditions that might evolve in EICP, therefore reducing the number of repeated CTs or anticipating the diagnose of EICP as compared to clinical observation alone. Examples of such conditions are a cerebral hemorrhage or the malignant middle cerebral artery infarction. We believe the present study is a fundamental step in these directions.

Conclusions

The US ONSD measurement, with a 5.5 mm cut-off, might safely be used to rule out EICP in patients with traumatic and non-traumatic brain injury in the ED.

This information may be particularly valuable when the time to CT must be prioritized, such as during mass casualty events, or in settings without readily access to CT.

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