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Reliability Evaluation of Temnography for Early Detection of Intracranial Lesions in Mild Traumatic Brain Injury Patient: A Preliminary Report of a New Portable, Non-Invasive Device

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Purpose: Mild Traumatic brain injury is classified based on Glasgow Coma Scale (GCS 13–15), it also involves transient alteration of brain function, which may lead to severe short- and long-term sequelae. When treating a patient with a mild head injury outside the hospital, it is of crucial importance to decide whether to transport him to a center without neurosurgery or to a center equipped with neurosurgery (primary centralization). Recent decades have seen exploration of portable, non-invasive devices for intracranial injury and stroke detection, with microwave frequency electromagnetic field technology showing promising clinical outcomes. This clinical investigation aims to assess the diagnostic accuracy of the TES HT100 medical device, utilizing electromagnetic fields for endocranial lesion screening.

Patients and Methods: Patients with mild traumatic brain injury were randomly enrolled according to inclusion criteria. Twenty-three patients recruited from the Intensive Short-Term Observation (ISTO) unit at San Donato Hospital in Arezzo. The sensitivity and specificity of the TES HT were evaluated statistically against cranial computed tomography (CT), the gold standard.

Results: A preliminary analysis shows a sensitivity of 100% and a specificity of 100%. Based on these results, there is maximum concordance between the two examinations, and the AUC is 1. No adverse events related to the use of TES HT100 or the examination.

Conclusion: The device's ability to differentiate patients with intracranial lesions from those without can streamline the diagnostic and therapeutic process, potentially leading to improved patient outcomes. If Temnography will maintain high standards of sensitivity and specificity with the expansion of the enrolled population, it could be considered as a stable screening tool in the Emergency Room (ER). We could think to apply this technology to reduce the length of stay that patients with mTBI have to spend in ER for observation. Temnography could also be useful in special categories of patients such as pregnant women or the pediatric population. Moreover, another front of future development of this technology could be extending the study to include Territorial Emergency. In this context, Temnography could aid centralized decision-making in patient care.

Keywords: temnography, mild traumatic brain injury, mTBI, traumatic brain injury, TBI, emergency medicine, pre-hospital

Introduction

Incidence of mTBI is 200–300/100,000 persons per year for hospitalized patients, not counting all those cases not calculated as untreated in the emergency department, primary care, urgent care, or those that go untreated at all. In the most developed countries, a decrease in incidence has been recorded in recent years, probably linked to the improvement

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of road safety, whereas the incidence of head injuries related to accidental falls has increased, probably linked to the increase in average age.[1]

Traumatic brain injury is classified based on Glasgow Coma Scale (GCS) scores into mild (GCS 13–15), moderate (GCS 9–12), and severe (GCS < 8), assessed within 30 minutes of trauma or upon presentation to the emergency department. Mild traumatic brain injury, also known as concussion, involves transient alteration of brain function, which may lead to severe short- and long-term sequelae. The underlying pathology ranges from temporary alteration of intracellular ion concentrations to permanent structural damage. In mild traumatic brain the ion shift causes a momentary functional alteration, the symptoms resolve quickly and concussive damage does not lead to any structural damage. However, even minor insults can cause an overregulation of the ion channels, making the brain vulnerable to hyperactivation, neuronal toxicity and cell death. This creates an altered metabolism during which neuronal dysfunction persists until recovery occurs. The most significant alterations in case of mild traumatic brain are minor alterations of cognitive functions that may occur immediately, but also after days or weeks. Structural abnormalities are not always visible to instrumental examinations, but at the histopathological level microscopic damage can be present.[2,3]

mTBI symptoms can be somatic, cognitive, sleep, and emotional. Somatic symptoms include headache, dizziness, diminished balance, vertigo, tinnitus, sensitivity to light and noise, nausea, and vomiting. Cognitive symptoms include impaired memory or concentration, delayed language comprehension, and slowed or repetitive speech. Emotional disturbances include irritability, sadness, anxiety, and depression. Sleep-related disturbances include the spectrum between insomnia and fatigue.[4] Subsequent hours and days may also witness mood and cognitive disturbances, light and noise sensitivity, and sleep disturbances.[5]

CT scan of the head is the diagnostic standard for acute evaluation of suspected traumatic intracranial injuries in the ED. However, CT is associated with exposure to ionizing radiation and higher health-care costs. Several clinical decision rules have been prospectively derived and validated to reduce the need for CT scanning and identify mTBI patients at risk for intracranial lesions and neurosurgical intervention.

The most widely researched clinical decision rules for mTBI are the Canadian Computed Tomography Head Rule (CCHR) and New Orleans Criteria (NOC). For patients with minor head injury and GCS score of 15, the CCHR and the NOC have equivalent high sensitivities for need for neurosurgical intervention and clinically important brain injury, but the CCHR has higher specificity for important clinical outcomes than does the NOC, and its use may result in reduced imaging rates.[6]

Among the radiological investigations, if indicated, the one that generally comes first is the non contrast CT of the head, whose objective is to exclude serious traumatic intracranial lesions in mTBI. However, it may happen that some patients, especially those who present significant neurological symptoms, do not present alterations on the CT scan. About a quarter of patients with concussion with a negative CT present pathological changes (eg micro-hemorrhages) on MRI.[7]

Despite the rarity of neurosurgical intervention candidates, prompt transfer to a suitable hospital is crucial since intracranial hemorrhage, if present, is a time-dependent pathology. Out-of-hospital treatment includes maintaining systolic blood pressure at 110 mmHg with 0.9% saline infusion to manage hypotension resulting from significant bleeding and scalp wounds.

No validated clinical criteria currently exist for primary centralization to a neurosurgical hub in mild traumatic brain injury cases that are found in out-of-hospital scenarios. Recent decades have seen exploration of portable, non-invasive devices for intracranial injury and stroke detection, with microwave frequency electromagnetic field technology showing promising clinical outcomes.

The use of the TES-HT100 device fits into this context, it is a medical device designed for non-invasive detection of endocranial lesions. We opted to use this device in the out-of-hospital scenario because it is a portable instrument, which uses non-ionizing radiation and returns a response in just a few minutes.

This clinical investigation aims to assess the diagnostic accuracy of the TES HT100 medical device, manufactured by B&B Srl, utilizing electromagnetic fields for endocranial lesion screening. Sensitivity and specificity were evaluated statistically against cranial CT, the gold standard, among 23 patients recruited from the Intensive Short-Term Observation (ISTO) unit at San Donato Hospital in Arezzo, following predefined inclusion/exclusion criteria.

Presentation of the TES-HT Model 100 Device

The TES-HT model 100 device (Figure 1) is a medical device designed for non-invasive detection of endocranial lesions. It utilizes non-ionizing electromagnetic waves at very low power (250 mW delivered discontinuously over

Figure 1 TES HT100 is a compact, lightweight instrument easily transportable to the patient's bedside.

a 5-minute examination), within the frequency range of 500–6500 MHz. This device is based on an innovative technology called Temnography, which exploits the dielectric and electromagnetic coefficients inherent to blood or brain tissue. By emitting specific electromagnetic waves at defined frequencies, it detects disturbances in the electromagnetic fields caused by intracranial alterations in both time and space domains. These data are collected and interpreted by an algorithm, yielding diagnostic results. The technical parameters of the instrument fall well within the safety limits required for devices utilizing radio frequencies, allowing its use without specific limitations or precautions. Thus, examinations with the TES HT100 can be safely repeated multiple times for both operators and patients. The device has obtained CE marking, indicating compliance with the essential safety requirements set forth by the EU under Regulation (EU) 2017/745, considering the inherent risk of the product, and is in accordance with IEC 60601-1 standards.[8,9]

The device is designed to indicate the possible presence of one or more intracranial lesions in a Yes/No format. The TES HT100 is a compact, lightweight instrument easily transportable to the patient's bedside, equipped with an internal rechargeable battery. A complete examination takes approximately five minutes, with four minutes allocated to data acquisition and around one minute for processing. It is important to stress that, due to its nature, the TES HT100 can only detect the presence or absence of at least one lesion and does not differentiate between lesion types. An initial study evaluating the sensitivity of TES HT demonstrated a 100% sensitivity of the device based on 98 patients with ischemic or hemorrhagic stroke, where TES HT examination was compared with cranial CT.[10]

Materials and Methods

This study, sponsored by B&B Srl, was approved by the Regional Ethics Committee for Clinical Experimentation of the Tuscany Region, Italy (CEAVSE). It was conducted in accordance with Good Clinical Practice ISO 14155 and Regulation (EU) 2017/745, following the guidelines for clinical investigation outlined in MEDDEV 2.7/1 rev. 4. All patients were recruited at San Donato Hospital in Arezzo, during the period from June 2023 to January 2024. Written informed consent was obtained from all participants, administered by the investigators before any study-related procedures were initiated. The inclusion and exclusion criteria are detailed in Table 1. Specifically, in the study are excluded pregnant women, patients with age inferior to 18 years old and patients with skull metallic prostheses because they interfered with the TES HT100 analysis.

Table 1 Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Age > 18 years	Age <18 years
Acquired informed consent	Pregnant women
Mild head trauma	Metallic prostheses in the skull

Study Aims

The research aims to:

1. Detect concordance of diagnostic performance of TES HT versus cranial CT. Identification of sensitivity and specificity values of the instrument compared to cranial CT, along with calculation of ROC curve and AUC.
2. Establishing the safety of the instrument by collecting data on hypothetical adverse events during its use in the study, determining their frequency and severity.

Patients were randomly enrolled according to inclusion criteria.

The study enrolled patients randomly referred to the Intensive Short-Term Observation (ISTO) unit at San Donato Hospital in Arezzo that met the study's inclusion criteria.

Results

Since June 2023, 23 patients with mild traumatic brain injury (14 females and 9 males) have been enrolled, with an average age of 83 years (range 73–98 years) and they all have met the inclusion/exclusion criteria of the study protocol and provided informed consent (Table 2). All patients underwent the standard diagnostic and therapeutic pathway for traumatic brain injury, including cranial CT examination, and subsequently underwent TES HT100 examination during the observation period in the ISTO unit. Three patients (numbers 6, 15, and 22) were excluded from the analysis of results because their TES HT100 examinations were not retrievable, likely due to a device storage error.

Table 2 Summary of Enrolled Patients

# Patient	Gender	Age	TES HT Result	TC Scan Result	Comparison	Note
1	♀	92	+	+	TP	Chronic vascular encephalopathy
2	♂	89	+	+	TP	Chronic ischemic microvascular leuko-encephalopathy
3	♀	91	+	+	TP	
4	♂	67	+	+	TP	
5	♀	98	–	–	TN	

(*Continued*)

Table 2 (Continued).

# Patient	Gender	Age	TES HT Result	TC Scan Result	Comparison	Note
6	♀	77		+	out	TES HT test not saved
7	♀	90	–	–	TN	
8	♂	83	+	+	TP	
9	♂	89	–	–	TN	
10	♀	93	–	–	TN	
11	♀	95	+	+	TP	
12	♂	73	+	+	TP	
13	♀	73	–	–	TN	
14	♀	88	–	–	TN	
15	♂	83		+	out	TES HT test not saved
16	♀	80	+	+	TP	
17	♂	76	+	+	TP	Chronic vascular leukoencephalopathy with macroangiopathic characteristics
18	♀	85	+	+	TP	Diffuse hypodensity chronic vascular encephalopathy
19	♀	79	+	+	TP	

(*Continued*)

Table 2 (Continued).

# Patient	Gender	Age	TES HT Result	TC Scan Result	Comparison	Note
20	♂	86	+	+	TP	Diffuse hypodensity chronic vascular encephalopathy
21	♀	83	+	+	TP	
22	♂	75		+	out	TES HT test not saved
23	♀	76	+	+	TP	

TES HT100 examinations were performed in most cases within 24 hours of cranial CT examination in the emergency department. In Figure 2 there is an example of TES exam compared with head CT.

The number of true positive cases (TP), defined as the number of patients with brain lesions correctly identified by the device and confirmed by CT, was 14. The number of false-negative cases (FN), defined as the number of patients with brain lesions not identified by the device but confirmed by CT, was 0. The number of true negative cases (TN), defined as the number of patients without brain lesions correctly identified by the device and confirmed by CT, was 6. The number of false-positive cases (FP), defined as the number of patients without brain lesions identified as positive by the device but confirmed as negative by CT, was 0 (Figure 3). A preliminary analysis on 20 patients shows a sensitivity of 100% and

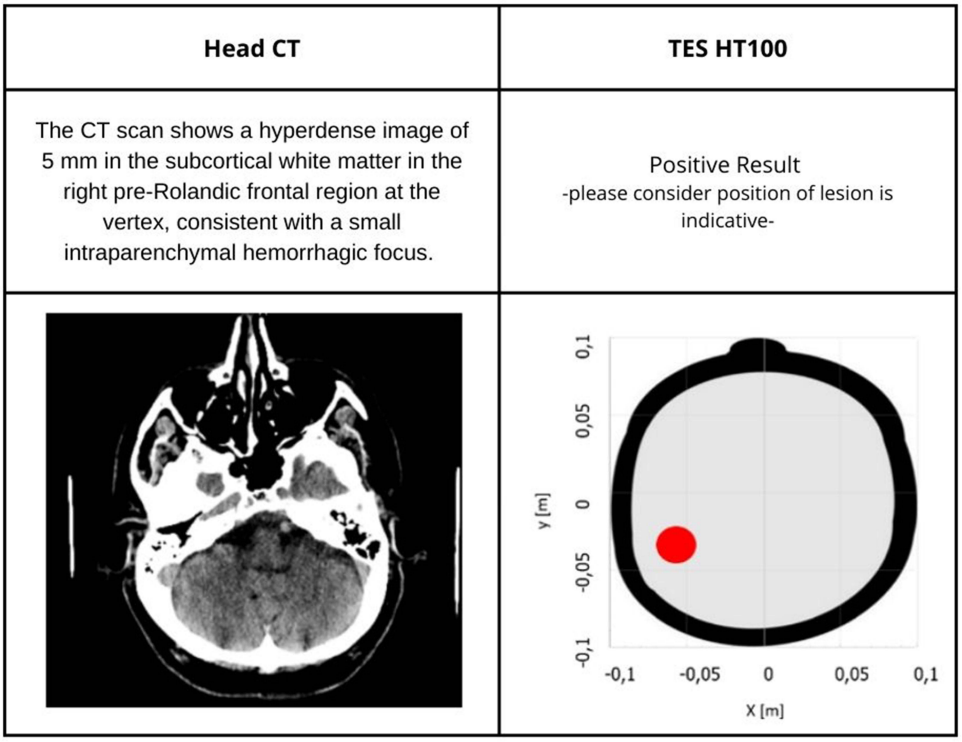

Figure 2 Comparison of CT result and TS HT100 result in pts 11 according to protocol.

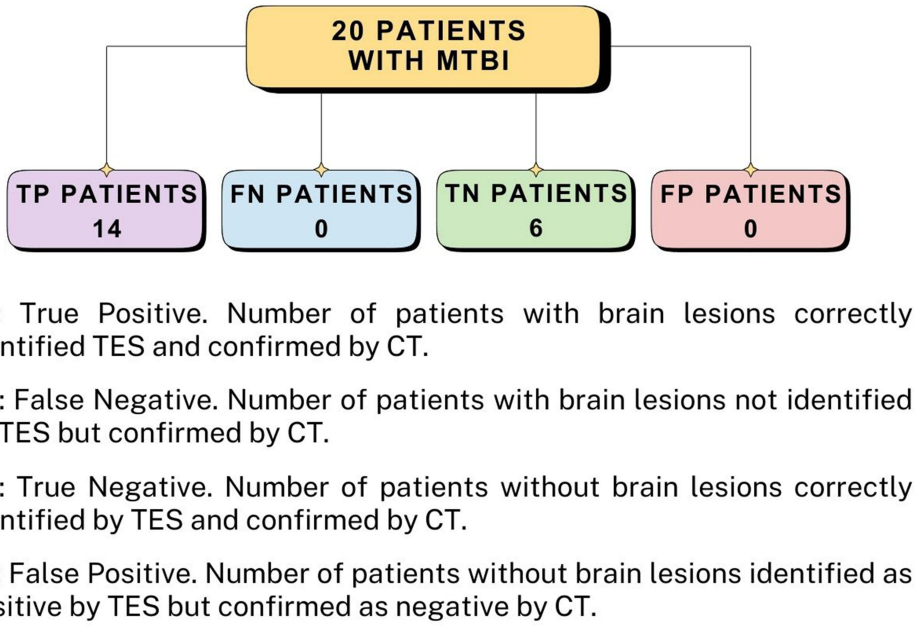

Figure 3 Synthesis of the comparison between cranial CT and TES HT 100 exams.

a specificity of 100%. Based on these results, there is maximum concordance between the two examinations, and the AUC is 1. No adverse events related to the use of TES HT100 or the examination, which required an average time of 5 minutes as indicated in the user manual, were detected.

Discussion

The TES HT100 is unable to distinguish whether brain lesions are acute or not, but solely detects their presence or absence. Therefore, in elderly patients like those enrolled in this study, the likelihood of pre-existing lesions or significant structural alterations, often associated with neurodegenerative conditions, is high. Indeed, in some patients where no trauma-related lesions were detected by cranial CT, significant areas of hypodensity related to previous ischemic/hemorrhagic events prior to the traumatic brain injury were found (patients' number 1, 2, 17, 18, and 20). Temnography in these cases yielded positive results as it was able to detect abnormalities in brain tissue signal compared to normal tissue. As evident in Table 1, the TES HT 100 examination was positive in cases 1, 2, 17, and 18 due to the presence of numerous hypodensity areas related to previous vascular sequelae defining a significant picture of advanced encephalopathy, and in case 20 due to an extensive previous vascular outcome in the context of advanced vascular encephalopathy. At the same time, it is interesting to stress that in some negative TES examination patients was found hypodensity due to non-pathological chronic vascular insufficiency correlated with the particularly advanced age of the examined patients.

This aligns with our initial aim of identifying endocranial lesions in patients with mild traumatic brain injury. The instrument, based on preliminary data collected in the hospital setting, represents an excellent screening method for endocranial lesions, with extremely high sensitivity and specificity. Future steps should be directed towards expanding the population to analyze a wider variety of cases, allowing for the evaluation of sensitivity and specificity in a larger and more heterogeneous population. It is hoped that in the future, TSE HT100 will be able to identify not only the presence or absence of lesions but also their nature.

Lastly, it should be emphasized that no adverse events occurred during the study. None of the enrolled patients reported discomfort or experienced complications after undergoing the TES HT100 examination.

Study Limitation

One of the main limitations of the study is the inability of the diagnostic method to clearly distinguish between acute hemorrhagic lesions and extensive vascular sequelae of previous injuries. This aspect should not be identified as a failure of the

technique but rather as further impetus for expanding the study population. The technique indeed offers analyzable software that can be improved based on the amount of collected data. An artificial intelligence capable of increasing discriminative power in direct proportion to the breadth of the case history. Certainly, we will need to make corrections for the next set of data we will collect. Specifically, we plan to focus on a category of patients with mild traumatic brain injury who present a Modified Rankin Scale (mRS) between 0 and 2. These are the patients who primarily determine whether centralization from the territory to the hospital with neurosurgery facilities or transportation to the hospital without neurosurgery facilities is appropriate in cases of suspected acute post-traumatic lesions. The idea is to more accurately select the population affected by mild traumatic brain injury to precisely adapt to the cohort of patients who, in reality, would be those whom health-care professionals would consider for centralization and who would likely benefit from improved prognosis and time to treatment if primary transportation were directed towards the hospital with the most appropriate resources. This new inclusion criterion would likely allow us to limit the interference of identifying pre-existing brain lesions. Indeed, the cases in which the TES HT100 yielded positive results for brain lesions not related to post-traumatic bleeding, were all related to patients with significant cognitive decline due to previous vascular outcomes with hypomobility syndrome and mRS > 2. These are patients who, in everyday reality, we would direct to the nearest hospital if they had mild traumatic brain injury. For all these reasons, it would be helpful to examine younger age groups (for example, between 18 and 80 years old) with mTBI and a mRS<2 in which we do not expect to find pre-existing brain lesions.

Conclusion

This study aimed to assess the diagnostic accuracy of the TES HT 100 device in detecting brain injuries among patients with mild head trauma, compared to cranial CT scans, considered the gold standard method. The analysis involved 20 patients recruited from Short Intensive Hospital Observation San Donato di Arezzo, based on predefined inclusion/exclusion criteria, has highlighted a sensitivity of 100% and a specificity of 100%, indicating the ability of the device to detect and recognize the presence of alterations in brain tissue compared to normal tissue. Notably, all patients identified as positive by the TES HT 100 device exhibited confirmed brain lesions on cranial CT scans, while those testing negative showed no signs of brain injury on CT scans. Although the device cannot differentiate between acute and chronic injuries, nor extensive vascular lesions from previous events, the findings support its routine use in screening for intracranial lesions among head trauma patients. For a future better application of temnography like a screen tool we will test the device in a younger group of patients with mTBI (for example, between 18 and 80 years old).

The device's ability to differentiate patients with intracranial lesions from those without can streamline the diagnostic and therapeutic processes, potentially leading to improved patient outcomes. If Temnography will maintain high standards of sensitivity and specificity with the expansion of the enrolled population, it could be considered as a stable screening tool in the Emergency Room. In particular, we could think to apply this technology to reduce the length of time that patients with mTBI have to spend in ER for observation. Temnography could also be useful in special categories of patients such as pregnant women or the pediatric population.

Moreover, another front of future development of this technology could be extending the study to include Territorial Emergency. In this context, Temnography could aid centralized decision-making in patient care. This direct use of the device on the field by emergency personnel, in addition to standard evaluation, holds promise for prognostic improvement and reduced treatment time, ensuring prompt referral to the most suitable facility.

Abbreviations

CT, computed tomography; GCS, Glasgow Coma Scale; TP, true positive; TN, true negative; FP, false positive; FN, false negative; ISTO, Intensive Short-Term Observation; MRI, magnetic resonance imaging; CCHR, Canadian CT head rule; NOC, New Orleans criteria; NEXSUS, National Emergency X-Radiography Utilization Study; mRS, Modified Rankin Scale.

Ethics Approval and Consent to Participate

Ethics approval was acquired by the ethics committee CEASVE (number of protocol 01022). We were allowed by the dataset owner to use the information in databases for the purposes of the research. The present study involved the use

of confidential or sensitive personal health information therefore the patient consent was required. The study was conducted in compliance with the Helsinki Declaration of 975, as revised in October 2013 and all data were kept anonymous.

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Dedicated to those who carry out research in Emergency Medicine.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no conflicts of interest in this work.

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