RESEARCH ARTICLE

HT TEMNOGRAPHY INTHEEARLY DIAGNOSIS OF BRAIN LESIONS DUE TO ISCHEMIC OR HEMORRHAGIC SROKE

Sebastiano Vaia[1], Alessandro Iavarone[4], Francesca Caterino[1], Carlo Strube[2], Elisabetta Garofalo[4], Maria Sannino[4], Nadia Gamboz[3], Daniela Rigatti[3] and Alessia Senese[3]

1. Casa di Cura Villa delle Magnolie.
2. Istituto Neurodiagnostico Vaia.
3. Università Suor Orsola Benincasa.
4. UOC di Neurologia, Ospedale CTO, AORN "Ospedali dei Colli", Napoli.

……………………………………………………………………………………………………....

Manuscript Info

……………………….

Abstract

………………………………………………………………

Background and aim: The efficacy of treatment in brain stroke is strictly time-dependent, and the development of rapid and non-invasive neurodiagnostic tools for the identification of brain lesions is crucial. Here we assess sensitivity, specificity, accuracy and safety of a new technology, the "TESHT" temnograph, in the identification of brain lesions in comparison to traditional CT and MRI scans. The temnograph is based on microwave emissions and requires the use of a light headset, representing a significant advancement in non-invasiveness and cost-effectiveness of neuroimaging diagnostics.

Methods: Ninety-eight nursing home patients (48M, 50F, age:30-85) with ischemic or hemorraghic stroke and a recent MRI and/or TC scan underwent a TESHT scan. The accuracy, specificity, sensitivity of brain lesions identification was compared between the 3 scans.

Results: In relation to the previous CT or MRI scans, TESHT showed 100% sensitivity, specificity and accuracy in the detection of prior and recent brain lesions. Moreover, the absolute safety of the tool was confirmed (100%), with no adverse events reported either by patients or technicians.

Conclusions: The TESHT temnograph appears to be a highly promising tool for the faster and less invasive diagnosis of brain lesions secondary to stroke, compared to traditional neuroimaging tools such as MRI and CT. Its accuracy, sensitivity and specificity in diagnosis indicates TESHT as a significant advancement in neuroimaging technology, allowing earlier and safer diagnosis in of cerebrovascular diseases.

……………………………………………………………………………………………………....

Introduction:-

Data from epidemiology show that strokes in 2019 caused 6.55 million deaths (84.2 per 100.000), resulting the second cause of death after ischemic cardiopathy, with an incidence of 12.2 million cases (150.8 per 100.000) and a prevalence of 101 million cases (1240.3 per 100.000). The most frequent type is ischemic stroke, which caused 3.29 million deaths (43.5 per 100.000), with an incidence of 7.63 million cases (94.5 per 100.000) and a prevalence of

Corresponding Author:- Sebastiano Vaia
Address**:-** Casa di Cura Villa delle Magnolie.

77.2 million cases (951 per 100.000). Ischemic stroke is followed, in frequency, by intracerebral hemorrhage, accounting for 2.89 million deaths (36 per 100.000), with an incidence of 3.41 million cases (41.8 per 100.000) and a prevalence of 20.7 million cases (248.8 per 100.000), and subarachnoid hemorrhage, which caused 373,00 deaths (4.7 per 100.000), with an incidence of 1.18 million cases (14.5 per 100.000) and a prevalence of 8.4 million cases (101.6 per 100.000).

The fifth edition of the European Cardiovascular Disease Statistics reports that stroke is the second cause of death in Europe, being responsible for 405,00 deaths (9%) in men and 583,000 (13%) in women.

In 2019, Italy registered 86,360 acute hospitalizations for stroke (code 014 – Intracranial hemorrhage or Cerebral Infarction). ISTAT data of the same year show that cerebrovascular diseases (most of them consisting of brain stroke) are, in Italy, the second cause of death, after ischemic heart diseases, causing 55,434 deaths (8.8% of all deaths), namely 22,062 among males (7.3%) and 33,372 among females (10.1%). Mortality rate for brain stroke is estimated at 20-30% 30 days by stroke and at 40-50% one year later. Moreover, disability persists in different grading of impairment in 75% of survivors, half of them exhibiting significant loss of self-sufficiency.

The prevalence and incidence of brain stroke increase with age, especially after 55; by age 65, the increase of incidence becomes exponential. It is evident that brain stroke represents an important public health issue, both because of its high prevalence and incidence, and the severity of its consequences for the patients, their families and caregivers, as well as because of the high social and financial burden it entails.

In the last decades, there have been significant improvements in the efficacy of preventive, therapeutic and welfare interventions focused on stroke and its risk factors, including the setup, across Italy, of several Stroke Units. Thanks to these advancements, a progressive reduction of the incidence and mortality of cerebrovascular diseases has been observed.

Considering that the efficacy of treatment in stroke is strictly time-dependent, rapid identification of brain lesions is critical to minimize cell damage and initiate pharmacological treatment as quickly as possible.

Since its foundation, aim of the B&B company has been the devising of non-invasive neurodiagnostic tools. After several years of trials B&B has created and patented a 1st class electromedical technology, named "temnography", as tool for diagnosis in General Medicine (certified by the Italian Public Health Ministry on October 23rd, 2021). Temnography employs electromagnetic fields to obtain brain tissue images. Compared to other neuroimaging techniques, the temnograph (TES, i.e., Subcranic Encephalic Temnograph) entails lower risks (it does not produce ionizing radiation) and is easy to use since it consists of a portable headset (weighting about 5 kg) and requires very little training to be manged.

The specific devices as yet derived from this technology are the "TESA", aimed to diagnose an ongoing brain hemorrhage (dynamic process), and the "TESHT", for the diagnosis of recent or prior brain lesions.

Here we assess sensitivity, specificity, accuracy and safety of the "TESHT" temnograph in the identification of brain lesions in comparison to CT and MRI scans in a sample of adult patients with diagnosis of ischemic or hemorrhagic brain stroke.

Methods:-
Participants
Participants were recruited from the nursing home "Villa delle Magnolie", of Castel Morrone (Caserta), Italy. They were selected according to: diagnosis of admission (ischemic or hemorrhagic brain stroke), age (18-90 years), comorbidities, availability of a recent brain MRI or CT scan. The final sample consisted in 98 patients (48F, 50 M, age 30/85).

Procedures:-
The TESHT scan was administered to the participants lying in their beds in supine position. The scan lasted 5 minutes (4 minutes of recording and 1 of data processing).

The computerized TES_HT scans were later compared to images of the same participant's brain obtained through either MRI or CT.

All participants and/or relatives have been aware of efficacy and safety of the procedures by a neurologist. All patients gave informed consent to the study, which was carried on according to the Declaration of Helsinki.

TheTES-HT   ***headset***

Data analysis
Images derived from the TESHT scan were compared with those from the same patient's CT or MRI scan with regard to sensitivity and specificity in the detection of brain lesions. Accuracy of the specific localization of the lesions was also compared between scans. The safety of the TESHT scan was also verified by assessing the presence of adverse events in both patients and technicians.

Results:-
In relation to the previous CT or MRI scans, TESHT showed 100% sensitivity and specificity in the detection of prior and recent brain lesions. Accuracy of lesion identification was also 100%. Finally, the tool also gave100% safe, since no adverse consequence was observed in either patients or technician. The full agreement between the methods of brain imaging led useless the Received Operating Curve analysis (ROC) to confirm the results.

Discussion:-
In this study we assessed sensitivity, specificity, accuracy and safety of a newly patented technology, the TESHT temnograph, for the detection of brain lesions due to stroke. With reference to traditional brain neuroimaging tools assumed as the gold standard in the detection of stroke lesions, namely MRI and CT, TESHT showed 100% overlapping with the former. The significance of these results is evident when considering the high practicality of this tool as if its safety. Indeed, compared to CT, the temnograph does not emit ionizing radiation; rather, it works by microwave emissions. Furthermore, it does not require the cumbersome equipment of traditional neuroimaging scanners. Specifically, the tool consists in a light headset that can be easily set up by a technician. This allows a relevant advancement in the timely detection of brain lesions. In Italy, the average waiting for a CT or MRI scan of a patient in a Neurology ward is about 60-180 minutes. The use of the temnograph would allow a significant shortening of waiting times, which appears crucial for highly time-dependent treatments as brain stroke is. Furthermore, its practicality and ease of use would meaningfully increase patient compliance.

In conclusion, our data show that the TES_ìHT temnograph is a sensitive, specific, accurate and safe instrument for the diagnosis of brain lesions. Its introduction in routine neurological care would represent a significant advancement in neuroimaging technology allowing for earlier, safer and cost-effective diagnoses in the field of cerebrovascular diseases.

Bibliografia:-
References
1.   Nikolova N.K.: 'Microwave imaging for breast cancer', IEEE Microw. Mag., 2011, 12, (7), pp. 78–94
2.   Fear E.C., Meaney P.M., Stuchly M.A.: 'Microwaves for breast cancer detection?', IEEE Potentials, 2003, 22, (1), pp. 12–18
3.   Fhager A., Persson M.: 'A microwave measurement system for stroke detection'. Seventh Loughborough Antennas and Propagation Conf., LAPC 2011, Loughborough, 14–15 November 2011
4.   Tian Z., Meaney P.M., Pallone M.J., ET AL.: 'Microwave tomographic imaging for osteoporosis screening: a pilot clinical study'. Conf. Proc. IEEE Engineering in Medical and Biology Society, 2010, pp. 1218–1221
5.   Jafari H.M., Deen M.J., Hranilovic S., ET AL.: 'A study of ultrawide- band antennas for near-field imaging', IEEE Trans. Antennas Propag., 2007, 55, (4), pp. 1184–1188
6.   Flores-Tapia D., Pistorius S.: 'Real time breast microwave radar image reconstruction using circular holography: a study of experi- mental feasibility', Med. Phys., 2011, 38, pp. 5420–5431
7.   Meaney P.M., Goodwin D., Golnabi A., ET AL.: '3D Microwave Bone Imaging'. Proc. Sixth European Conf. on Antennas and Propagation (EUCAP), 2011, pp. 1170–1171
8.   Solimene R., Ruvio G., Dell'Aversano A., ET AL.: 'Detecting point- like sources of unknown frequency spectra', Prog. Electromagn. Res., 2013, B, (50), pp. 347–364
9.   Ruvio G., Solimene R., Cuccaro A., ET AL.: 'Breast cancer detection using interferometric MUSIC: experimental and numerical assess- ment', Med. Phys., 2014, 41, (10), pp. 103101/1–103101/11
10.   Gabriel C.: 'Compilation of the dielectric properties of body tissues at RF and microwave frequencies'. Report N.AL/OE-TR- 1996-0037, Occupational and Environmental Health Directorate, Radiofrequency Radiation Division, Brooks Air Force Base, Texas (USA), June 1996
11.   Gabriel C., Gabriel S., Corthout E.: 'The dielectric properties of bio- logical tissues: I. Literature survey', Phys. Med. Biol., 1996, 41, pp. 2231–2249

12.   Gabriel S., Lau R.W., Gabriel C.: 'The dielectric properties of bio- logical tissues: II. Measurements in the frequency range 10 Hz to 20 GHz', Phys. Med. Biol., 1996, 41, 2251–2269

13.   Solimene R., Cuccaro A.: 'Front wall clutter rejection methods in TWI', IEEE Geosci. Remote Sens. Lett., 2013, 11, pp. 1158–1162

14.   Coincecao R.C., O'Halloran M., Glavin M., ET AL.: 'Comparison of planar and circular antenna configurations for breast cancer detection using microwave imaging', Progr. Electromagn. Res., 2009, 99, pp. 1–20

15.   R. Scapaticci, O. M. Bucci, I. Catapano, L. Crocco, "Differential Microwave Imaging for Brain Stroke Followup", International Journal of Antennas and Propagation, vol. 2014, Article ID 312528, 11 pages, 2014. https://doi.org/10.1155/2014/312528.

16.   Chew,W.C. Waves and Fields in Inhomogeneous Media; IEEE Press: New York, NY, USA, 1995.

17.   Schmidt,R.MultipleEmitterLocationandSignalParameterEstimation. IEEE Trans. Antennas Propag. 1986, 34, 276–280.

18.   Ruvio, G.; Cuccaro, A.; Solimene, R.; Brancaccio, A.; Basile, B.; Am- mann, M.J. Microwave bone imaging: A preliminary scanning system for proof-of-concept. IEEE Healthc. Technol. Lett. 2016, 3, 218–221.

19.   Ruvio, G.; Solimene, R.; Cuccaro, A.; Gaetano, D.; Browne, J.E.; Am- man, M.J. Breast cancer detection using interferometric MUSIC: Experi- mental and numerical assessment. Med. Phys. 2014, 41, 102101–102111

20.   R. Solimene, and A. Cuccaro, "Front Wall Clutter Rejection Methods in TWI," IEEE Geoscience and Remote Sensing Letters, Vol. 11, 1158- 1162, 2013.

21.   A. Cuccaro, A. Dell'Aversano, G. Ruvio, J. Browne, R. Solimene, "Incoherent Radar Imaging for Breast Cancer Detection and Experi- mental Validation Against 3D Multimodal Breast Phantoms," Journal of Imaging, 7 (2), 23, 202

22.   Tivive, F.H.C.; Amin, M.G.; Bouzerdoum, A. Wall clutter mitigation based on eigen-analysis in through-the-wall radar imaging. In Pro- ceedings of the 2011 17th International Conference on Digital Signal Processing (DSP), Corfu, Greece, 6–8 July 2011; pp. 6-8.

23.   Ruvio, G.; Solimene, R.; Cuccaro, A.; Fiaschetti, G.; Fagan, A.J.; Cour- nane, S.; Cooke, J.; Ammann, M.J.; Tobon, J.; Browne, J.E. Multimodal Breast Phantoms for Microwave, Ultrasound, Mammography, Magnetic Resonance and Computed Tomography Imaging. Sensors 2020, 20, 2400.

24.   P.M.Meaney,T.Zhou,M.W.Fanning,S.D.Geimer,andK.D.Paulsen, "Microwave thermal imaging of scanned focused ultrasound heating: phantom results," International Journal of Hyperthermia, vol. 24, no. 7, pp. 523–536, 2008.

25.   Haynes M, Stang J, Moghaddam M. Real-time microwave imaging of differential temperature for thermal therapy monitoring. IEEE Trans Biomed Eng. 2014;61(6):1787-1797. doi:10.1109/TBME.2014.2307072

26.   M. Guardiola, L. Jofre, S. Capdevila, S. Blanch, and J. Romeu, "UWB brain differential imaging capabilities," in Proceedings of the European Conference on Antennas and Propagation (EuCAP '12), Prague, Czech Republic, 2012

27.   N.Joachimowicz,B.Duchene,C.Conessa,O.Meyer,"Anthropomorphic Breast and Head Phantoms for Microwave Imaging,"Diagnostics (Basel) vol.8, pp.1-12, 2018.

28.   T.P. Marsland and S. Evans, "Dielectric measurements with an open- ended coaxial probe," Microwaves Antennas and Propagation, vol. 134, pp. 341-349, 1987.

29.   Manuale di Neurologia, Corrado Angelini , Esculapio

30.   Salute e governo.it.