ePIC

Non-invasive Continuous Intracraneal Pressure Monitoring

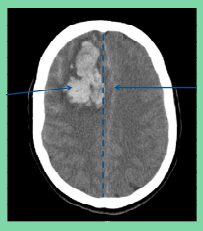
Summary

Intracranial pressure (ICP) monitoring is performed through invasive methods which require a surgical procedure. These methods entail several complications even becoming **life-threatening**.
In order to abolish the above mentioned complications and to **save on the sanitary cost**, we present a non-invasive **method based on electroencephalographic (EEG) recordings**. Our results from simultaneously recording EEG and ICP on intensive care unit patients have demonstrated a **relationship between both datasets**.
The aim of the present proposal is **to change the actual evaluation of brain state in critically ill patients** from intensive care unit (ICU), by assessing directly the **brain activity** rather than measuring other indirect measures, such as the ICP. Moreover, this **non-invasive technology** could expand the monitoring technique to other patients.

The context

High intracraneal pressure is seen in 50% of Head traumas and subarachnoid haemorrhage and in:

- Hydrocephalus
- Intracranial tumours
- Hepatic encephalopathy
- Cerebral oedema



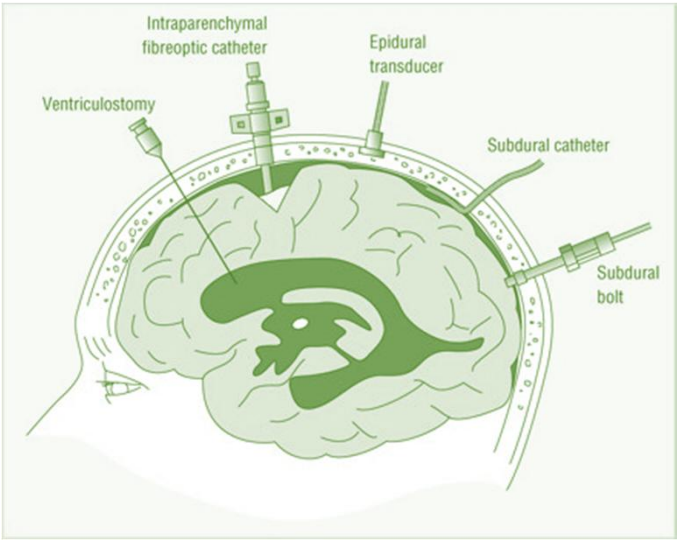
Leading to:

- Devastating neurological damage reducing cerebral perfusion pressure (less blood reaches the brain)
- Cerebral ischemia (brain cells with no oxygen)
- Herniation of the brainstem or other vital structures
- Death

High ICP has a 20% mortality rate

The state of the art

ICP monitoring is done **invasively**, introducing a catheter inside the brain. Current techniques:



The problem

1. Highly complex surgery is mandatory to introduce the sensors within the intracranial space.
2. Complications during its use can be seen in up to a 20% of the interventions.
3. Its implantations through the brain tissue can produce haemorrhages.
4. Risk of infection that increases dramatically each day that the patient has the catheter inserted (monitoring over days).
5. Technical failures due to obstruction or malposition are extremely common, which usually produce a high variability on the measurements, generating low quality data that cannot be trusted.
6. Only big hospitals can use current techniques due to the need of surgery room, ICU and qualified personnel.

The team

This project has been developed by a multidisciplinary team including **clinicians**, such as intensivist, neurosurgeons and neurophysiologist; and also **Data Analysts** from the Data Analysis Unit of the hospital. This last unit has been the coordinator of the project and has developed **the software´s code** of the invention and **setting up the ICP-EEG system**.

Solution and Technology

Our work on the analysis of simultaneous recordings of EEG and ICP from patients suffering traumatic brain injury (TBI) and subarachnoid haemorrhage (SAH), hospitalized in the ICU at the Hospital de la Princesa has allowed us to **demonstrate the existence of a direct, although non-linear, relationship between the dynamics of the ICP and variables derived from the EEG recordings.** This is the first time that both ICP and EEG are simultaneously recorded and the analysis of more than 1500h of recording also suggest that it is possible **to anticipate the ICP rising,** and thereby, allowing the physicians to act consequently to prevent this pathological change. In addition, the sampling frequency of our method is higher than the commonly used sensors, allowing in this way to **perform numerical calculations in very short temporal windows**. Therefore, these results have taught us that **it is possible to infer the ICP dynamics** without the need to insert a sensor into the brain tissue.

3rd party or own sensors: non invasive monitoring system (that acquires, stores, processes and, eventually, sends) the biophysical signals from the user (EEG helmet)

Algorithm: to calculate both univariate and multivariate measures over the electroencephalographic recordings from patients in order to infer the ICP; Main value of our project; already tested with positive results

APP: Simple user interface collects information and shows relevant patient data and results that arise from algorithms analysis (continuous ICP based on EEG data)

The proprietary algorithm is a mature technology after 3 years of research, and it has been tested in different contexts. The results are published in high-impact international journal* and we plan to perform a multicentric study by this year. **Our Software technology presents a TRL7. A Spanish patent application (P201730943, 07/18/2017) and a PCT (ES18070334) have been filed by Fundación del Hospital Universitario de la Princesa, including myself and the other researchers from the team as inventors.**

* Ancor Sanz-García *et al* 2018 *J. Neural Eng.* **15** 066029

Competitors

Several methods of non-invasive measurements of ICP were developed in the last years, as for instance transcranial ultrasonography, jugular bulb oxygen saturation or tympanic membrane displacement. However, all of these non-invasive methods are still in a phase of **technical evaluation**. Moreover, all of them estimate the ICP through an indirect variable and **do not allow a continuous measure of the ICP**.

Potential impact

Nowadays ICP is monitored in several pathologies, such as traumatic brain injury, hydrocephalus and subarachnoid hemorrhage, tumor, encephalitis or meningitis. Some of these pathologies will present a high incidence in the near future. According to GlobalData Database, Neurological Diagnostic Equipment category was €616,4 million in 2017 with 4.10% CAGR (2016-2023). However, due to the **paradigm change** that we expect due to the non-invasive functioning of the system, **those numbers could increase exponentially**.

Competitive advantage

Benefits for patients:

- Scalp (wireless) electrodes instead of an intracranial sensor
- Abolishing the risk of infections
- Freedom of movements and place of analysis
- Measuring continuously the ICP in awake, not anesthetized or sedated patients = more accurate data
- Ambulatory ICP monitoring becomes a real possibility taking into account the current wide availability of wireless electrodes and the low cost of the same.

New business opportunities:

- Small hospitals with little resources
- Residences; elder patients
- Tele-monitoring and data sharing

Benefits for the public and private healthcare systems:

- Eliminate an unneeded surgery
- Save costs derived from the professionals working-hours and surgery complications
- Lack of need of neurosurgery room or ICU patient control
- Cheaper measuring sensors and equipment
- Increased quality of the service and differential value against competitors

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