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CHALLENGE 1: Optimisation of continuous monitoring of strokes in Neuro-Vascular Units (OSCAR)

Institution responsible for the Challenge

Name of the institution: FOCH Hospital

Service/Department: Neurology

Pitch

Optimisation of continuous monitoring of strokes in Neuro-Vascular Units

Motivation and description

Strokes are a public health issue given their frequency and neurological sequels: the leading cause of death for women in France and the leading cause of acquired adult disability (Chevreul 2016). The annual cost of healthcare for strokes was estimated at €5.3 billion in 2007, representing 3% of health expenditure in France. Many advances have been made: the creation of Neuro-Vascular Intensive Care Units, stroke plans and the development of thrombectomy since 2015. However, patients who have suffered strokes are at high risk of neurological complications, including an increase in ischemic territory or a haemorrhagic complication (Davenport 1996). Several studies have shown that variations in physiological parameters, in particular hemodynamic and respiratory parameters, can modify the evolution of the stroke.

Thus, changes in arterial pressure during thrombectomy and the early phase of cerebral infarction affect the prognosis of patients and more generally that of patients having suffered from a stroke (Aslanyan 2004 - Whalin 2017 - Lowhagen 2015). Oxygen saturation should be maintained in the acute phase of cerebral infarction above 94%, and the temperature below 38° C, warranting close monitoring of "pulsated" oxygen saturation (SpO2). These elements were highlighted this year through the Guidelines for the Early Management of Patients With Acute Ischemic Stroke (Powers 2018).

Neuro-Vascular Intensive Care Units (NVICU) allow for hospitalisation in a monitored structure of patients with or without a thrombectomised stroke under the supervision of a neurologist on call, and a registered nurse for 4 beds (day and night). 8 beds at night). However, there is a lack of continuous data on all hospitalisation from arrival at the Emergency Department until exit from the NVICU.

This situation leads to the inability to detect early and correctly treat a complication before it leads to a worsening of the patient's health (Ghaferi 2009). Thus, although abnormal vital signs that can identify clinical deterioration appear minutes to hours before a serious adverse event occurs, they often go undetected because of intermittent monitoring, including in Continuous or Intensive Care Units. (Franklin 1994 - Buist 1999 - Hodgetts 2002 - Bell 2006). In addition, the risk is increased during the night (Churpek 2017).

The occurrence of a serious adverse event may be partly explained by delayed or incorrect medical management (Brennan 1990). Setting up teams to provide rapid response is designed to improve the safety of hospitalised patients whose condition is deteriorating.

These systems are based on the identification of patients at risk and the rapid response of the team ("Rapid Response Team"). They have been established in many countries and the United States (Winters 2006 - Steel 2008). A synthesis was performed by Jones et al. in 2011 (Jones 2011).

The "challenge" concerns patients hospitalised following a stroke and is therefore to document non-invasively and continuously the hemodynamic and respiratory anomalies from their arrival at the Emergency Reception Service until their exit from the Neuro-Vascular Intensive Care Unit (NVICU). This will provide important data on possible anomalies that may require treatment and that would have gone unnoticed.

Scope

The problem is the same for all health facilities providing care for patients who have suffered a stroke. Currently, in France, 137 Neuro-Vascular Units are accredited for the care of stroke patients. The objective of our work is to assess within a Neuro-Vascular Unit (> 1,200 strokes/year) the contribution of continuous monitoring of the main parameters leading to the aggravation of our patients and which can allow the early management of complications occurring immediately after a stroke.

Operational Requirements

The evolution of technology offers the possibility of having a digital solution to allow to obtain physiological data continuously.

One of the most studied connected objects is a piezoelectric sensor without contact, because it is placed under the mattress, which constantly measures the heart rate and the respiratory rate. A study of 2,314 medical-surgical patients showed that such monitoring is associated with a significant decrease in the number of calls for cardiac arrest and length of stay in hospital (Brown 2014). More recently, the use of wireless sensors to monitor vital signs, such as SpO2, heart rate, blood pressure and respiratory rate, has led to the automatic calculation of an alert score and has been associated with a significant decrease in the number of cardiac arrests and mortality (Subbe 2017). Several sensors have been made available allowing wireless monitoring of outpatients (Michard 2017 - Ross 2017).

We want to have permanent measurement of several physiological parameters using a skin patch type of sensor. Indeed, there are sensors that allow the continuous measurement of several parameters and which transmit data to both a secure health data storage site and to a health professional.

This sensor should measure heart rate, blood pressure, respiratory rate, arterial oxygen saturation, temperature, and assess movement.

Such a device would make it possible:

- Firstly, to continuously document the hemodynamic and respiratory anomalies during the entire hospital stay: from arrival at the Emergency Reception Service until exit from the NVICU. This would provide important data on possible anomalies that may require treatment and that would have gone unnoticed.
- In a second step, to allow active management of these anomalies in the form of an equivalent to a "Rapid Rescue Team". The situation of the NVICU is unique in that a neurologist is on call but it is possible that abnormalities, potentially at risk, do occur and escape the healthcare team or are underestimated. Thus, the data provided to the healthcare team (the registered nurse and neurologist) would complement the data usually collected.

Operational requirements include the use of reliable connected objects (Beg 2017 - Leth 2017) (Cadmus-Bertram 2017 - Wang 2017), providing secure circuit and storage of medical information that can be analysed and transmitted as almost real-time alerts to the healthcare team.

Expected impact

The introduction of rapid response teams within a health facility is controversial. Their introduction was motivated by several monocentric "before/after" studies (Bellomo 2003 - Foraida 2003 - Jones 2005 - Buist 2007 - Sebat 2007 - Sharek 2007). These studies have shown a significant number of interventions and a reduction in the rate of cardiac arrests (Jones 2009). However, the multi-centre clinical trial MERIT (Medical Early Intervention and Therapy), randomised in clusters, failed to demonstrate such a benefit (Chen 2008). In addition, the results of the meta-analyses questioned the existence of benefits and suggested that further research is needed (McGaughey 2007 - Ghan 2010). However, de Jong's summary in 2016 showed that the implementation of a medical emergency team is associated with a significant decrease in the overall and unexpected mortality of hospitalised patients (de Jong 2016).

We want to assess a device for continuous skin patch measurement of several physiological parameters (heart rate, blood pressure, respiratory rate, arterial oxygen saturation, temperature) and movement in a specific patient population: stroke patients.

The main objective is to compare the data usually collected with those obtained by this innovative technique. The related indicator is the number of elements carrying the risk of aggravation of the stroke (hypo- or hyper-tension, hypoxemia or hyperthermia, for example) detected earlier owing to continuous monitoring.

The first secondary objective is to develop alerts from these continuously measured data after developing specific algorithms, to provide them to the healthcare team and to assess any changes in care. The related indicators are the number of alerts created and the therapeutic changes.

The second secondary objective is to assess whether the provision of alerts and the resulting therapeutic changes improve the prognosis of patients, including the reduction of neurological sequels, sources of deterioration of quality of life and additional costs for the company. The related indicators are: average length of stay in a Neuro-Vascular Unit, clinical severity score at discharge or J7 (NIHSS score), modified RANKIN disability score (mRS, ordinal analysis) and the EuroQoL quality of life score (EQ-5D) at three months.

Feasibility

The Neuro-Vascular Unit at the Foch Hospital is the only neurology department and the only neuro-vascular unit in the Department of Hauts-de-Seine (1.6 million inhabitants), with over 1,200 stroke patients admitted in 2017. The Unit has already demonstrated its strong adaptability to digital projects (patient file management, treatments and complementary digital examinations). The Neuro-Vascular Unit is staffed by a clinical research nurse and a full-time Clinical Research Associate who can ensure the implementation of a digital assessment. Data collected (blood pressure, SpO2, temperature) from patients who have suffered a stroke have been entered prospectively since 2013 into a secure database.

The implementation of a digital solution for continuous multimodal monitoring will be integrated into the expertise of the Neuro-Vascular Unit, which is also demonstrated by its recent publications (Gory 2018 - Dargazanli 2017 - Escalard 2018). The future deployment of the digital tool will benefit from the research network of the Information Processing and System Teams (ETIS), coordinated by Dr. LAPERGUE, Head of the FOCH Hospital Neuro-Vascular Unit.