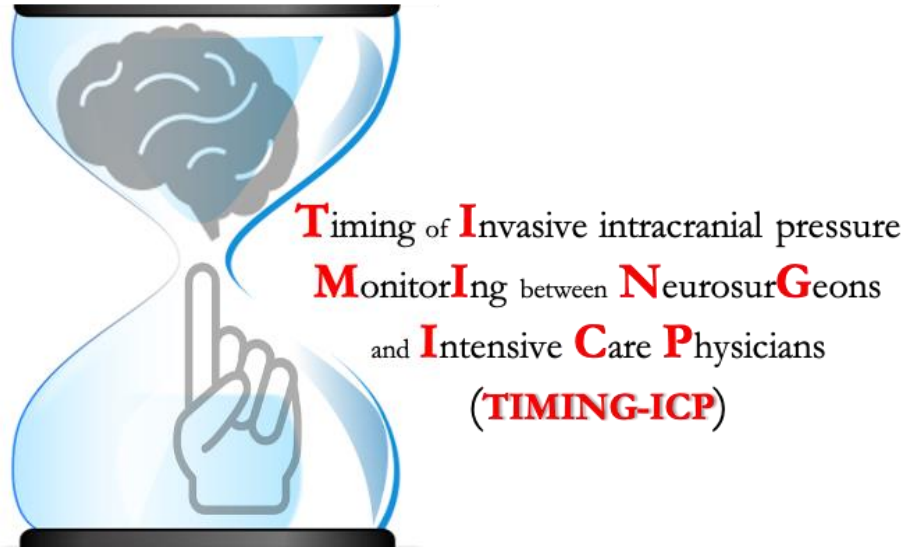

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Introduction

Invasive intracranial pressure monitoring takes on essential importance in patients with traumatic brain injury and in all cerebral pathologies in which intracranial hypertension is the main cause of death[1].

The dose of intracranial pressure (ICP), meant as the time for which intracranial pressure exceed the reference values, has been related to poor outcome[2,3]. "Time is brain" is a concept which highlights the importance of preempt and perform the proper therapeutic strategies, in order to reduce complications in the context of a rapidly and irreversibly compromised cerebral tissue as a result of a brain injury.

On these bases, it is essential to perform an accurate intracranial pressure monitoring as soon as possible, to detect and possibly treat intracranial hypertension, which would definitively compromise brain parenchyma.

Invasive intracranial pressure monitoring performed by placing an intracerebral catheter (intraventricular or intraparenchymal) is currently the gold standard technique for continuous ICP invasive monitoring.

This maneuver has usually been performed by neurosurgeons, but in an effort to optimize as much as possible the timing of ICP monitoring, reducing time between urgent request for invasive ICP monitoring placement and the placement itself, this procedure (specifically intraparenchymal catheter placement) has more often been carried out by intensive care physicians at the bedside, in the last few years[4-7].

In the setting of clinical practice, multidisciplinary management of intracranial pressure handling and treatment is therefore achieved by joint decisions between neurosurgeons and intensive care physicians, but differences in logistic matters and in the executive availability could impact on the dose of intracranial pressure to which patient is exposed.

The aim of this study is to compare timing of invasive intracranial pressure monitoring placement performed by intensive care physicians and neurosurgeons and to detect possible differences in the incidence of complications between the two groups.

Aim of the study

Primary outcome:

- To compare timing of invasive intracranial pressure monitoring performed by intensive care physicians and neurosurgeons, from time T1 (defined as the moment in which invasive intracranial pressure monitoring indication is stated) to time T2 (skin incision).

Secondary outcome:

- Comparative evaluation of post-procedural complications (meningitis, catheter-placement related bleedings, wrong placement) between intensivists and neurosurgeons
- Length of ICU stay, length of hospital stay, duration of mechanical ventilation, Glasgow Outcome Score at 3 months.
- To compare timing and complications of invasive intracranial pressure monitoring between placement of intraparenchymal catheters and extraventricular drains

Materials and methods

Inclusion criteria:

- All patients with acute cerebral pathology with urgent indication to invasive intracranial pressure monitoring (intraparenchymal and intraventricular)
- Age greater than or equal to 18 years

Exclusion criteria:

- Patients in whom indication to intraventricular catheter placement is stated for reasons other than the need of ICP monitoring (e.g. CSF drainage)
- Patients in whom indication to invasive intracranial pressure monitoring is not an urgent request
- Patients in whom a significative coagulation disorder is a contraindication for procedure

Timings are defined as:

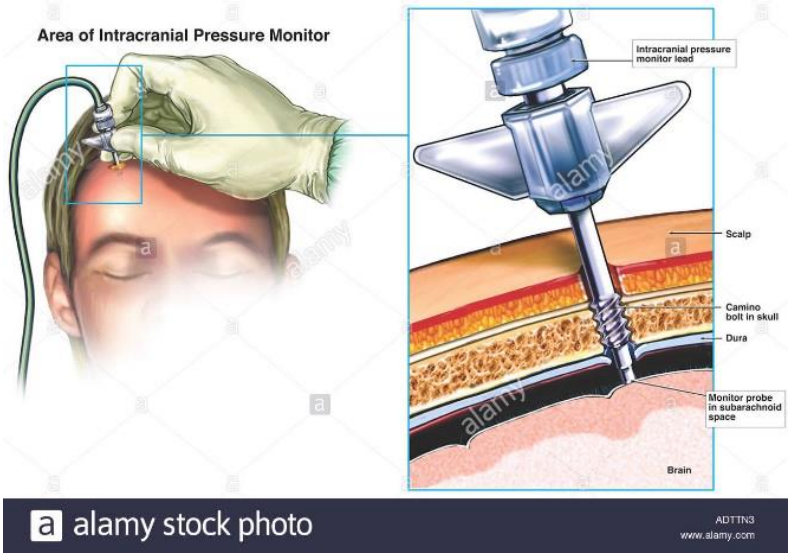
- T0: suspect of pathology at risk for developing intracranial hypertension
- T1: neurointensive and neurosurgical indication to invasive ICP monitoring (it could be the time when brain CT is performed or, in the absence of a brain CT, the time at which indication to invasive ICP monitoring is stated)
- T2: skin incision at skull for BOLT/EVD placement

Place of positioning:

The place (intensive care unit or operating room, specifying if it's a dedicated OR or a surgical unit) where the procedure is carried out must be declared.

Complications which will be analyzed:

- Catheter-related intracranial bleedings, with or without the need of neurosurgical operation (all the patients enrolled in the study must have been screened for coagulation disorders)
- Meningitis (actually related to procedure), with microorganism causing meningitis demonstrated by culture (not a contaminant microorganism)
- Wrong positioning of catheter and/or its malfunction (e.g., a correct placed catheter penetrates the parenchyma for few millimeters/absence of ICP wave). Malfunction is considered as such if it occurs up to 12 hours after placement.



Statistical analysis plan

Delta time in the placement of invasive ICP monitoring is assumed as T2-T1, declared in minutes.

Typology operator (neurosurgeon vs intensivist) impact on delta time will be evaluated through a multilevel model elaborated with a linear mixed model. The model will assume the center in which the maneuver is carried out as clustering factor. The place where the maneuver is carried out (intensive care unit vs operating room) and the confidence in performing the procedure (routine vs sporadic, defined as less than 5 times a year) will be assumed as covariates.

The incidence of complications, valued as a binary variable, will be evaluated through logistic model GLMM (generalized linear mixed model) with the organization exposed in the dedicated data element.

Sample size assessment

Sample size assessment has been performed by Monte Carlo simulation (B=500). Assuming a timing decrease (T2-T1) of 20 minutes in the procedure carried out by an intensivist compared to a neurosurgeon, with a mean time of 100 minutes, a standard deviation between center and intra-center of 10 minutes, 16 centers, each one with the same number of patients and a balance 1:1 between the two groups (intensivist:neurosurgeon), a total number of 64 patients (32 treated by intensivists and 32 by neurosurgeons), it allows to evaluate the interest effect with a power of at least 95%, and a significance level of 5%.

This elevated power has been decided according to the simplicity of the assumed design (same number of entities and conditions for center) and not evaluable in his real configuration.

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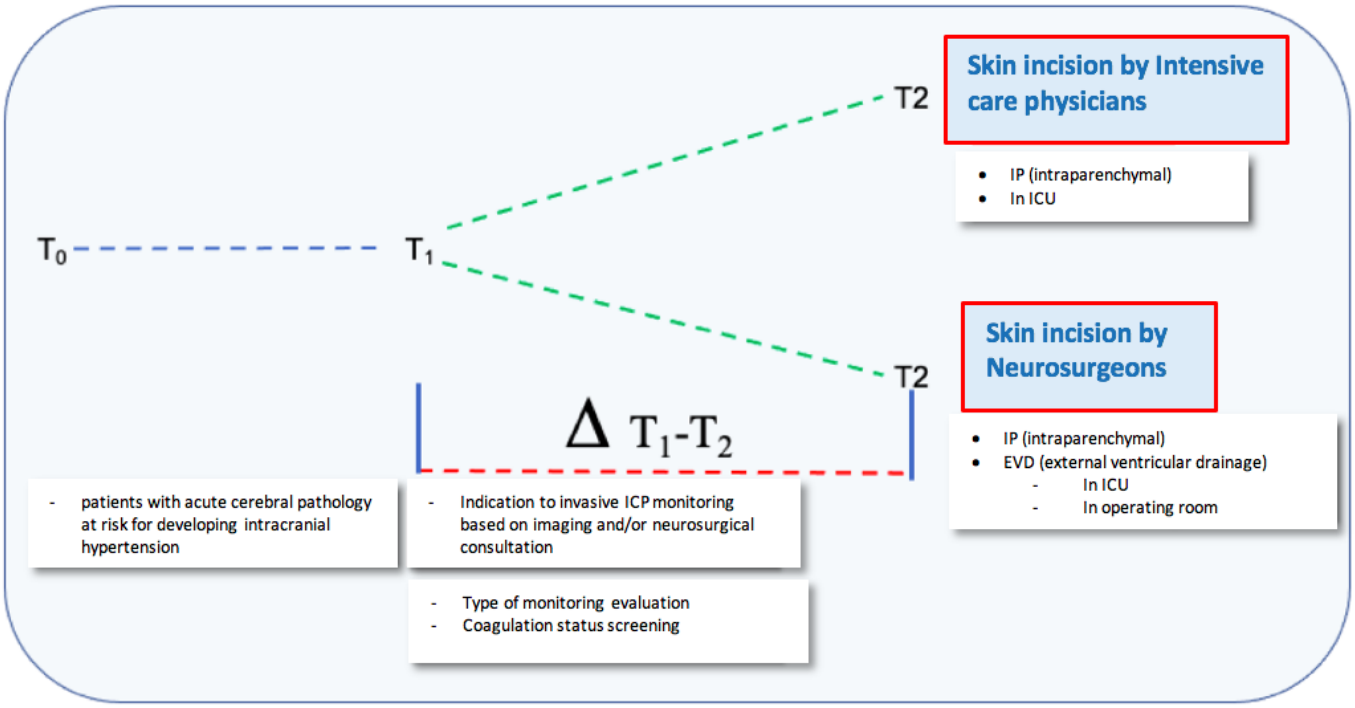
Time-line


Skin incision by Intensive care physicians
T2
IP (intraparenchymal)
In ICU
T0
T1
Skin incision by Neurosurgeons
T2
Δ T1-T2
IP (intraparenchymal)
EVD (external ventricular drainage)
In ICU
In operating room
patients with acute cerebral pathology at risk for developing intracranial hypertension
Indication to invasive ICP monitoring based on imaging and/or neurosurgical consultation
Type of monitoring evaluation
Coagulation status screening