Safety Profile of an Intracranial Multimodal Monitoring Bolt System for Neurocritical Care: A Single-Center Experience

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Abstract

Background

Intracranial multimodality monitoring (iMMM) is increasingly used in acute brain injured patients; however, safety and reliability remain major concerns to its routine implementation.

Methods

We performed a retrospective study including all patients undergoing iMMM at a single European center between July 2016 and January 2020. Brain tissue oxygenation probe (PbtO₂), alone or in combination with a microdialysis catheter and/or an 8-contact depth EEG electrode, was inserted using a triple lumen bolt system and targeting normal-appearing at risk brain area on the injured side, whenever possible. Surgical complications, adverse events and technical malfunctions, directly associated with iMMM were collected. A blinded imaging review was performed by an independent radiologist.

Results

113 patients with 123 iMMM insertions were included for a median monitoring time of 9 [3–14] days. Of those, 93 (76%) patients had only PbtO₂ probe insertion and 30 (24%) had also microdialysis and/or iEEG monitoring. SAH was the most frequent indication for iMMM (n = 60, 53%). At least one complication was observed in 67/123 (54%) iMMM placement, corresponding to 58/113 (51%) patients. Misplacement was observed in 16/123 (13%), resulting in a total of 6/16 (38%) malfunctioning PbtO₂ catheters. Intracranial hemorrhage was observed in 14 iMMM placements (11%), of which one required surgical drainage. Five placements were complicated by pneumocephalus and 4 with bone fragments, none of these requiring additional surgery. No CNS infection related to iMMM was observed. Seven (6%) probes were accidentally dislodged and 2 probes (2%) were accidentally broken. Ten PbtO₂ probes (8%) presented a technical malfunction after a median of 9 [ranges: 2–24] days after initiation of monitoring and 4 of them were replaced.

Conclusions

In this study, a high occurrence of complications related to iMMM was observed, although most of them did not require specific interventions and did not result in malfunctioning monitoring.

Introduction

Acute brain injury (ABI), such as traumatic brain injury (TBI) and subarachnoid hemorrhage (SAH) are important causes of mortality, morbidity and economic burden worldwide [5, 7]. Monitoring of

neurological function in ABI patients is mandatory to detect early neuro-worsening before irreversible damage occurs, to individualize and guide patients' care and to assess the effects of specific therapies [14].

Clinical examination is not always reliable in this setting, as some patients might be heavily sedated [2]. As such, specific neuro-monitoring tools can help to manage secondary brain injuries in these patients. In particular, invasive intracranial pressure (ICP) and derived cerebral perfusion pressure (CPP) are the cornerstone of neuro-monitoring in severe ABI patients, as reported by current guidelines [11], although mainly based on observational studies conducted in TBI patients [1, 3, 9]. Indeed a randomized control trial has failed to show any benefit of invasive ICP monitoring compared to clinical and imaging monitoring [4]. Moreover, in the era of precision medicine, a simplistic "one size fits all" strategy based only on fixed ICP/CPP target is not sufficient to optimize brain function; a complex tailored strategy for brain-injured patients based on multimodality monitoring and personalized integration of an array of data may be more adequate [15].

Intracranial multimodality monitoring (iMMM) has been implemented in many institutions, combining ICP monitoring with brain tissue oxygenation (PbtO₂) probes, microdialysis catheters (MD, to assess cerebral metabolism) and intracortical or surface electroencephalography (iEEG, to detect seizures or cortical spread depolarizations)[6, 15]. However, considering the unknown clinical significance of iMMM, concerns have been raised about its invasiveness, safety and technical reliability [2, 10].

As such, we aimed to evaluate a single-center experience about surgical placement and related complications, management, technical malfunctions, and adverse events of an iMMM implementation in ABI patients.

Methods

Study population

All patients who underwent ICP monitoring combined with iMMM (i.e. PbtO₂ ± MD and iEEG) placement at a single European academic center between July 2016 and January 2020 were eligible for the study. The study protocol was approved by the institutional review board (P2020/019), which waived the need for a written consent. Medical charts and brain imaging were retrospectively reviewed for data collection.

Invasive multimodality monitoring

A triple lumen bolt allowing the insertion of a PbtO₂ probe (IM3.ST_EU, Integra LifeSciences Corporation, Plainsboro, NJ, USA), alone (from July 2016 to December 2018) or in association (from January 2019 to January 2020) with an 8-contacts depth EEG electrode (Dixi Medical, Besançon, France) and a microdialysis catheter (M-Dialysis, Solna, Sweden), was placed in the operating room by a neurosurgeon in patients with ABI (i.e. TBI, SAH or intracranial hemorrhage, ICH), who had indications for ICP

monitoring (i.e. abnormal CT-scan findings and a Glasgow Coma Score on admission < 9). The triple lumen bolt placement is shown in Figure 1.

A single 1g dose of cefazolin was administered before incision with no continuation of prophylactic antibiotic afterwards. The bolt was positioned 1.5 cm anteriorly from the Kocher's point, targeting normal-appearing brain area of the injured side or, in case of surgical constraints (i.e. need for craniectomy, large intracranial hematoma, large hydrocephalus) in the contralateral side. In case of aneurysmal SAH, the bolt was positioned on either the ipsilateral side of the aneurysm (i.e. anterior circulation) or on the right side (i.e. no aneurysm identified or aneurysm located in the posterior circulation). For patients with delayed clinical deterioration without previous iMMM, the bolt was placed ipsilateral to the cerebral vasospasm and/or "at risk" area, as suggested by cerebral CT-scan perfusion. Drilling was performed using a manual craniotome assembled to a 5.3 mm twist drill-bit specifically designed. External ventricular drain (EVD) or intraparenchymal ICP monitoring were inserted through an adjoining distinct burr hole located at Kocher point.

Data collection and definitions

Demographics, indications for iMMM, severity scores on admission (Glasgow Coma Scale [19], Acute Physiologic Assessment and Chronic Health Evaluation -APACHE- II score[13], and Sequential Organ Failure Assessment -SOFA- score[20]) and hospital mortality were collected. Unfavorable neurological outcome was defined as a Glasgow Outcome Scale of 1-3 at hospital discharge. Working hours were defined from 8am to 6pm, Monday to Friday (excluding public holidays).

To describe iMMM-related events, surgical complications, adverse events and technical malfunctions were retrieved from medical records. Surgical complications were defined as: a) misplacement; b) intracranial hemorrhages (ICH); c) bone fragments; d) pneumocephalus and e) central nervous system (CNS) infections. Probe location in the subcortical anterior frontal area was considered as "optimal". Misplacement was therefore identified as non-optimally located probes, i.e. extra-axial, cortical matter, deep grey matter, paraventricular or intraventricular locations; ICH, bone fragments and pneumocephalus were identified on cerebral CT-scans performed after iMMM implementation, which were reviewed by a radiologist blinded to the outcome of the patient. Also, ICH were classified as Grade I (i.e. 1mL hemorrhage at any location along the iMMM), Grade II (i.e. 1mL hemorrhage at any location along the iMMM) or Grade III (i.e. >1mL hemorrhage at any location along the iMMM or in the ventricle but contiguous to the catheter tip [16]), adapting a proposed classification for EVD-related hemorrhages. CNS infections were defined as meningitis, encephalitis and/or ventriculitis with microbiological documentation on CSF samples and local skin infection and/or material culture of iMMM, as defined by the CDC/NHSN criteria [12] of hospital acquired infections. Adverse events included accidental dislodgement or breaking of any probe or bolt device, requiring replacement or withdrawal. "Technical malfunction" was defined in the absence of any surgical complication and inconsistent PbtO₂ values with the absence of PbtO₂ response to the increase of the fraction of inspired oxygen to 100% for 15 minutes (i.e. increase < 10 mmHg).

Statistical analysis

Descriptive statistics were computed for all study variables. A Kolmogorov-Smirnov test was used and histograms and normal-quantile plots were examined to verify the normality of distribution of continuous variables. Discrete variables were expressed as counts (percentage) and continuous variables as means $\pm$ SD or median [25th–75th percentiles]. Demographics and clinical differences between subgroups of patients (TBI vs non-TBI patients; iMMM with complications vs. no complication; iMMM placement in non-working hours vs. working hours; iMMM placement under antiaggregant/anticoagulant therapy vs. others; PbtO₂ alone vs PbtO₂+iEEG/MD) were assessed using a chi-square, Fisher's exact test, Student's t-test, or Mann-Whitney U test, as appropriate. A $p < 0.05$ was considered as statistically significant. All descriptive statistics and statistical analyses were performed using "R" version 3.6.1.

Results

Study population

A total of 113 patients (median age 52 [41-62] years; 57/113, 50% male gender) underwent 123 iMMM placements during the study period; of those, 93 (76%) patients had only PbtO₂ probe insertion and 30 (24%) had also microdialysis and/or iEEG monitoring. ICP was monitored in all patients. SAH was the most frequent indication for iMMM (n=56, 50%); 35 (31%) patients had TBI. Median GCS on admission was 7 [3-11]. Main characteristics of the study population are shown in Table 1.

iMMM and complications

Median duration of iMMM was 9 [3-14] days. Among the 10 patients that required a second iMMM (i.e. due to complications/malfunctioning in 8 and due to delayed new deterioration in 2), the placement occurred after 7 [3-9] days and numerically more frequent in SAH patients (n=7) than others (ICH, n=2; TBI, n=2). At least one complication was observed in 67/123 (54%) iMMM placement, corresponding to 58/113 (51%) patients. No significant differences were observed between patients showing at least one iMMM-related complications when compared to others (Table 1).

Misplacement was observed in 16/123 (13%) iMMM placements, consisting of 5 extra-axial (i.e. 4 subdural and 1 subarachnoid), 7 intra-axial (i.e. 6 paraventricular and one in deep grey matter) and 4 intraventricular probes. The 5 extra-axial probes and the single probe placed deeply in the grey matter were malfunctioning; all 6 paraventricular probes were functioning and gave consistent PbtO₂ values. The 4 intraventricular probes were successfully repositioned (with reliable PbtO₂ values) by unscrewing the bolt and at bedside without complications, resulting in a total of 6/16 (38%) malfunctioning PbtO₂ catheters in case of misplacement.

ICH was observed in 14 iMMM placements (11%), including 7 tract hemorrhages (6%, all Grade I; 3 of those PbtO₂ catheters were also malfunctioning), 5 extra-dural hematomas (4%, all Grade II; of which one required surgical drainage – one PbtO₂ catheters was malfunctioning) and 2 distal probe tip

hematomas (2% - all Grade I; no PbtO₂ catheter was malfunctioning). Only 2/14 (14%) patients who experienced ICH were under antiaggregant/anticoagulant therapy (OR for increased risk of ICH 0.74 [0.15-3.58], p=0.7 vs. patients without antiaggregant/anticoagulant therapy).

Five placements were complicated by pneumocephalus (4% - one PbtO₂ catheter was dysfunctional) and 4 with bone fragments (3% - one PbtO₂ catheter was dysfunctional); none of these complications required additional surgery. No CNS infection related to iMMM was observed. Seven (6%) probes were accidentally dislodged and, in 1 patient, the probe was replaced; 2 probes (2%) were accidentally broken and no replacement was performed.

Ten PbtO₂ probes (8%) presented a technical malfunction (i.e. not attributable to surgical complications/adverse events) after a median of 9 [ranges: 2-24] days after initiation of monitoring and 4 of them were replaced. All complications are summarized in Table 2. Table 2 also shows a comparison between normally functioning probes (n=101) and dysfunctional probes (n=22). The association of several complications is depicted in Figure 2.

iMMM and complications in subgroups

The distribution of complications was similar in TBI and in non-TBI patients. Similarly, there were no differences in the rate of complications according to time of iMMM placement (non-working hours vs. working hours). There were no significant differences in the rate of complications between iMMM with only PbtO₂ monitoring compared to iMMM including PbtO₂, microdialysis and/or iEEG (47/93, 51% vs. 20/30, 65%, p=0.22). These data are shown in table 3.

Discussion

In this study, we observed that surgical complications and adverse events were common after iMMM placement, in particular probe misplacement and small-volume intracranial hemorrhage. No infection related to iMMM was observed. The type of acute brain injury and the timing of placement were not associated with a higher occurrence of iMMM-related complications. Only a minority of these complications were associated with iMMM dysfunction.

The most investigated surgical complications related to iMMM are probe misplacement and intracranial hemorrhage. Placement of PbtO₂ probes outside the white matter, within a lesion or within a ventricle may yield irrelevant brain oxygen measurement and would result in additional costs (i.e. for probe replacement and/or because of lack of an adequate monitoring tool to guide interventions). Misplacement rates ranged from 0% to 14.3% across different studies [2, 8, 10, 17, 18] and varied depending on the targeted area of the brain (i.e. higher when the target was a contusional then a healthy brain area). In our cohort, 13% of iMMM placement was associated with probe misplacement. Although this is quite higher than in most of previous reports, we investigated a heterogeneous cohort of patients with different forms of brain injury, while most of other studies focused on TBI patients. Future

prospective studies evaluating with more accuracy the occurrence of iMMM-related complications should therefore include different forms of brain injury to better evaluate the potential role of the underlying disease in the occurrence of such complications.

Conversely, the occurrence of ICH was relatively low. In our series, where all patients underwent cerebral CT-scan after iMMM placement, tract and distal probe hemorrhages were evaluated by an independent radiologist who reviewed all postoperative imaging, including immediate post-placement but also delayed imaging studies. Moreover, only one case required surgical drainage (i.e. a compressive right parasagittal extradural hematoma). Dings et al. [8] described a similar occurrence of ICH due to placement of the PbtO₂ probes close to the sagittal sinus, which should require a particular attention from physicians placing iMMM. Considering the variable occurrence of ICH due to iMMM placement reported in the literature, ranging from 0% to 40.5% [2, 8, 10, 17, 18], large multicentric registries are required to better describe the occurrence of such complication, its localization and size, the consequences on patients' clinical status as well as related interventions.

We observed no infection related to the iMMM placement. In fact, infections due to this type of intraparenchymal monitoring appear to be rare: in the largest series available including 501 patients, only one infection was reported [2]. On the other hand, accidental dislodgment and probe breaking are usually reported, ranging from 5.9% to 7.4% and from 2.5% to 4.5%, respectively [2, 8, 10, 17, 18]. Whether these complications occur because of agitation or discomfort, during daily standard interventions (i.e. changes in bed positioning, physical therapy) or during transport (i.e. to perform brain imaging or other diagnostic/therapeutic procedures), it remains unclear from our retrospective data. Neuro-critical patients often require great manipulation and transportation which may make them vulnerable to these adverse events [10]. An interesting dynamic approach to adverse events was proposed by Foreman et al. [10], who quantified sudden stops of data recording as discontinuations, resulting either from dislodgement or unplugging by time tracking them as one-off events rather than only reporting their occurrence. During a median monitoring time of 97 hours, device discontinuation was noted in 25/43 (58%) patients and concerned the combined ICP/PbtO₂ probe in 7 (16%) cases, with a total of 4% of the recorded data considered as unusable. They also found a significant association between discontinuation and the number of patient trips for procedures or imaging.

Finally, despite complications and technical malfunctioning, iMMM appears to be safe, as only one additional surgery with no subsequent short-term neurological sequelae was observed. Moreover, both hospital mortality rate and neurological outcome were similar between patients that experienced at least one complication when compared to others. However, 10 (8%) probes presenting a technical malfunction independently from other complications and, in some cases, this occurred within the first week of monitoring. The additional costs for probe replacement as well as the immediate loss of relevant monitoring data in these patients should also be further evaluated in larger cohorts, as it might be important information for centers who would decide to initiate placing iMMM in their routine practice.

This study has some limitations due to its monocentric retrospective design, which limit the generalization of the main findings. Also, we did not specifically investigate long-term effects of the reported complications. Moreover, the role of neurosurgeons' skills was not considered into the analysis as iMMM placement was performed by rotating residents supervised by senior neurosurgeons with no main operator clearly identified into medical charts. Second, we used a triple lumen bolt device placed into the operating room and our findings do not apply to other possible solutions (i.e. double lumen bolts or subcutaneous tunelization without bolt) or setting (i.e. placement into the ICU and/or by a non-neurosurgeon). Third, the PbtO₂ was the sole modality concerned by technical malfunction report, as being the only one used in clinical routine (i.e. microdialysis and iEEG data were only collected for research purposes).

Conclusion

iMMM placement including PbtO₂ monitoring was associated with several mild complications but had an acceptable short-term safety profile in our institution. These data underline the need to standardize the reporting of technical and surgical iMMM complications to better evaluate its risk/benefit ratio. International collaboration through prospective multicentric data collection according to well-defined complications would promote the optimal use of iMMM.

Declarations

Funding

The research was not supported by any company. The devices were bought by the intensive care unit and the neurosurgery department to be used in a daily clinical practice.

Conflicts of interest/Competing interests

The authors declare that they have no conflict of interest.

Availability of data and material

All the data are available on demand to mejdi.albarajraji@gmail.com.

Code availability

Not applicable

Authors' contributions (optional: please review the submission guidelines from the journal whether statements are mandatory)

Not mandatory

Additional declarations for articles in life science journals that report the results of studies involving humans and/or animals

Not applicable

Ethics approval

Ethical approval was obtained from ethics committees of the Erasme Hospital, Free University of Brussels, Brussels, Belgium: file EC P2020/019.

Consent to participate

For this type of study formal consent is not required.

Consent for publication

Consent to submit has been received from all co-authors and responsible authorities at the institute/organization where the work has been carried out before the work is submitted.

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Tables

Table 1. Characteristics of the study population, according to the occurrence of invasive multimodal monitoring (iMMM) complications.

	ALL (n=113)	Without Complications (n=55)	With Complications (n=58)	P value
graphics				
gender, n (%)	57 (50)	28 (51)	29 (50)	0.99
median (IQR)	52 [41-62]	52 [42-60]	53 [41-65]	0.56
rbidities				
al Hypertension, n (%)	28 (25)	13 (24)	15 (26)	0.83
tes, n (%)	7 (6)	6 (11)	4 (7)	0.52
ic Heart Disease, n (%)	9 (8)	7 (13)	6 (10)	0.77
ous Neurological Disease, n (%)	2 (2)	2 (4)	3 (5)	0.99
, n (%)	7 (6)	5 (9)	3 (5)	0.48
cirrhosis, n (%)	1 (1)	0	2 (3)	0.50
r, n (%)	4 (4)	4 (7)	2 (3)	0.43
ic Renal Disease, n (%)	2 (2)	1 (2)	1 (2)	0.99
dmission				
HE II score , median (IQR)	19 [14-22]	20 [15-23]	18 [14-21]	0.38
score, median (IQR)	9 [6-11]	9 [5-10]	9 [7-11]	0.32
sion GCS, median (IQR)	7 [3-11]	6 [3-10]	8 [4-12]	0.12
lying Disease				0.28
(%)	35 (31)	17 (31)	18 (31)	
n (%)	56 (50)	29 (53)	27 (47)	
t (%)	20 (18)	7 (13)	13 (22)	
al, n (%)	2 (2)	2 (4)	-	
y ICU stay				
ressors, n (%)	110 (97)	55 (100)	55 (95)	0.24
pic agents, n (%)	36 (32)	15 (27)	21 (36)	0.32
anical ventilation, n (%)	113 (100)	55 (100)	58 (100)	0.99
replacement therapy, n (%)	3 (3)	0	3 (5)	0.99
mes				
ngth of stay, days	15 [9-23]	13 [7-20]	18 [11-30]	0.03
tal Mortality, n (%)	54 (48)	30 (55)	24 (41)	0.19
orable neurological outcome, n (%)	73 (65)	42 (76)	30 (53)	0.02

COPD: chronic obstructive pulmonary disease; ICU: intensive care unit; TBI: traumatic brain injury; ICH: intracranial hemorrhage; SAH: subarachnoid hemorrhage; SOFA: sequential organ failure assessment; APACHE : acute physiology and chronic health evaluation; IQR: interquartile range.

Table 2 : Complications, adverse and probe dysfunction events related to the placement of invasive multimodal neuromonitoring (n=123).

	All probes (N=123)	Normally functioning probes (N=111)	Mal functioning probes (N=22)	p- value
complications				
ment, n (%)	16 (13)	10 (10)	6 (27)	0.03
ial Bone s	4 (3)	3 (3)	1 (5)	0.71
cephalus	5 (4)	4 (4)	1 (5)	0.90
ction, n (%)	0	0	0	-
ial hemorrhage,	14 (11)	10 (10)	4 (18)	0.27
mplications				
l malfunction, n	10 (8)	0	10 (45)	-
Adverse events				
al dislodgement,	7 (6)			
of any probe or ce, n (%)	2 (2)			
ment required, n	9 (7)			

CNS: central nervous system

Table 3: Occurrence of complications according to some patients' characteristics at the moment of invasive multimodal monitoring (iMMM) placement.

	Non-TBI (N=86)	TBI (N=37)	P value	Non-working hours (N=46)	Working hours (N=77)	P value	No AP/AC (N=102)	AP/AC (N=22)	P value	PbtO ₂ alone (n=92)	Combined (n=31)	P value
one on, n	47 (55)	20 (54)	0.99	45 (58)	22 (48)	0.27	55 (55)	12 (55)	0.99	47 (51)	20 (65)	0.22
ent, n	13 (15)	3 (8)	0.39	10 (13)	6 (13)	0.99	15 (15)	1 (5)	0.30	14 (15)	2 (7)	0.35
ents,	3 (4)	1 (3)	0.99	3 (4)	1 (2)	0.99	4 (4)	0	0.99	2 (2)	2 (7)	0.26
halus,	4 (5)	1 (3)	0.99	4 (5)	1 (2)	0.65	5 (5)	1 (2)	0.58	2 (2)	3 (10)	0.10
%)	9 (11)	5 (14)	0.76	9 (12)	5 (11)	0.98	12 (12)	2 (9)	0.99	12 (13)	2 (7)	0.51
ent, n	4 (5)	3 (8)	0.44	6 (8)	1 (2)	0.26	5 (5)	2 (10)	0.35	4 (4)	3 (10)	0.37
1 (%)	2 (2)	0	0.99	0	2 (4)	0.14	1(1)	1 (5)	0.32	1 (1)	1 (3)	0.45
ient t (%)	7 (8)	2 (5)	0.72	5 (7)	4 (9)	0.72	4 (4)	5 (23)	0.009	6 (7)	3 (10)	0.69
al n, n	7 (8)	3 (8)	0.99	5 (7)	5 (11)	0.50	5 (7)	5 (11)	0.50	6 (7)	4 (13)	0.27

CNS: central nervous system; TBI: traumatic brain injury; AP = anti-platelet; AC = anticoagulant

Figures

Creation: original content, using commercially available photo editing software: Adobe Photoshop CS 6

Figure 1

Schematic illustration of the triple lumen iMMM bolt placement with its three probes (PbtO2, microdialysis and EEG).

Creation: original content, using commercially available text editing software: Microsoft Word

Figure 2

Association of multiple surgical complications and adverse events. ICH: intracranial hemorrhage; PN: pneumocephalus; BF: bone fragment.