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Improvised intracranial pressure monitoring devices for traumatic brain injury management in a low-income environment: A single-centre randomised study demonstrating feasibility

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ABSTRACT

Background: The high cost and non-availability of standard ICP monitoring devices limit their use in low- and middle-income countries like Nigeria. This study aims to demonstrate the use of an improvised intraventricular ICP monitoring device as a feasible alternative.
Research question: Are improvised ICP Monitoring devices feasible and effective in resource-constrained settings?
Materials and methods: The study was a prospective single-institution investigation involving 54 adult patients that presented with severe TBI (GCS of 3–8) within 72 h of injury and required operative intervention. All patients underwent craniotomy or primary decompressive craniectomy (DC) to evacuate traumatic mass lesions. 14-day in-hospital mortality was used as a primary endpoint of the study. 25 patients had ICP monitoring post-operatively using the improvised device.
Results: The modified ICP device was replicated using a feeding tube and a manometer with 0.9% saline as a coupling agent. Based on hourly ICP recording (up to 72 h), patients were observed as having high ICP (>27 cm H_2O) and normal ICP (27 cm H_2O). In the ICP-monitored group, raised ICP was detected more than in the clinically assessed group (84% vs 12% p= <0.001).
Discussion and conclusion: There was a 3-time higher mortality rate among the non-ICP monitored participants (31%) compared to the ICP-monitored participants (12%), although this did not reach statistical significance due to the small sample size. This preliminary study has shown that this modified ICP monitoring system is a relatively feasible alternative for diagnosing and treating elevated ICP in severe TBI in resource-constrained environments.

1. Introduction

Intracranial pressure (ICP) monitoring is integral to managing traumatic brain injury (TBI). Changes in ICP depend on factors such as the expansion of intracranial volume, the volume distribution of the components (brain, blood, cerebrospinal fluid (CSF), lesions, and oedema) and the elasticity of each element (Rosner and Daughton, 1990). This is well explained by the Monro-Kellie doctrine (Mokri, 2001). The outcome of severe TBI worsens when associated with an elevated ICP (Mokri, 2001; Saul and Ducker, 1982; Miller et al., 1977). Methods for ICP monitoring can be invasive or non-invasive. Invasive methods are reportedly the most accurate way to measure ICP because they provide direct signals from the intracranial compartment (Harary et al., 2018; Raboel et al., 2012).

Although Intracranial pressure (ICP) monitoring devices are standard in developed countries, these devices are not readily available in LMICs like Nigeria, primarily due to the cost. A National Health Insurance Scheme (NHIS) has been introduced recently, but it is yet to benefit most of the populace; hence, most people still pay for their health costs out-of-pocket. The standard device is simply out of the reach of the majority, where more than 70% of Nigeria's citizens earn less than $1.00 (N120.00) per day (Dauda, 2017). An effective way of addressing this problem is to ensure that the cheapest, most affordable, readily available and yet effective ICU monitor is considered when managing patients with traumatic brain injury.

Studies on indigenous ICP monitoring systems showed an economic advantage due to their low cost compared to the high cost of standard

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Abbreviation

ICP	Intracranial pressure
TBI	Traumatic brain injury
DC	Decompressive craniectomy
GCS	Glasgow coma score
CSF	Cerebrospinal fluid
IVD	Intraventricular device
IPD	Intraparenchymal device
LMIC	Low- and middle-income countries
CVP	Central venous pressure
ICU	Intensive care unit
CT	Computed tomography

intraparenchymal catheters (Muhamed1 et al., 2014; Hazarika et al., 2016). With the high burden of TBI in low- and middle-income countries (LMICs) all around the world, coupled with a lack of resources for adequate medical funding, and poor outcomes, this study was carried out to elaborate on the advantages of this improvised device with the use of available locally sourced and readily available resources to assist in the management of severe TBI patients.

2. Materials and methods

This prospective hospital-based study was carried out in the Lagos University Teaching Hospital, a large tertiary neurosurgical centre serving over 10 million people in Lagos, Nigeria. Patients were recruited for the study over one year between January 2017 to January 2018. Approval for the study was granted by the Lagos University Teaching Hospital research ethics committee. Informed consent was obtained from the caregivers of all patients recruited for the study. The outcome defined for this study was the 14-day mortality in both groups of randomised patients.

2.1. Eligibility criteria

Adult patients with severe TBI (GCS 3–8) aged 16–80 who had operative interventions were included in the study as they would need intracranial pressure monitoring for the first few hours (72 h in this study) following the procedure. Patients whose caregivers did not consent to the study, those with a GCS score of 3 with bilateral fixed dilated pupils, and those with penetrating and open head injuries were excluded. Patients who were known to have bleeding disorders or were on medication that could precipitate bleeding disorders and those with apparent systemic infection at presentation were also excluded.

2.2. Patient recruitment

Recruitment was done by the investigator and other senior registrars in the unit. Post-resuscitation GCS assessed by the admitting neurosurgical registrar was used to classify patients into mild, moderate and severe TBI. The patients were randomised into two groups. The ICP Monitored group (the group that had the improvised ICP monitor inserted) and the Non-ICP Monitored group (the group that did not have the improvised ICP monitor). The sample size was determined using the formula for comparing two independent group means.

$N = F(\alpha, \beta) \times 2\ (SD)^2/D^2$

Where N = minumum estimated sample size per group.

SD= Standard deviation of the outcome of interest
d = Smallest difference in mean that would be clinically significant to detect

At 5% significance and power of 90%, F (α, β) = 10.5
If d = 2.5 and SD = 2.5, then the minimum sample size of each group is
$N = 10.5 \times 2\ (2.5)^2/(2.5)^2$
N = 21

However, at least 25 patients were randomised into each group to account for an attrition rate of 20% during the study.

2.3. Indications

The types of surgery included a primary decompressive craniectomy with/without evacuation of the mass lesion or a craniotomy with evacuation of the mass lesion. The indications for surgery were based on clinical and radiological parameters assessed, including a drop in GCS of 2 or more points from admission/a motor score drop of 1 point, motor posturing, pupillary size changes (unilateral unreactive pupil), pulse rate, blood pressure and respiratory rate changes suggestive of clinical raised ICP. Radiological parameters included the presence of a mass lesion with evidence of raised ICP (significant midline shift, herniation, effaced or absent basal cisterns, and loss of surface sulci markings).

2.4. The modified ICP monitor set-up

A soft size 6 feeding tube was used as an intraventricular catheter at the surgery (Fig. 1). Following aseptic precautions, a free-hand Kocher's point ventricular cannulation (1–2 cm anterior to the coronal suture in the mid pupillary line and 3 cm lateral from the midline) was performed. The side of ventricular access was dependent on the more prominent and accessible ventricle on the initial CT scan, as well as an expectation that more expansion of the already compressed ventricle would occur following the evacuation of the mass lesion. An appropriate catheter length (5–6 cm) was placed into the ventricle with patency confirmed by CSF egress. The external end was then connected to the CVP manometer, with 0.9% saline used as a coupling agent (Fig. 2). Zeroing was done at the level of the external auditory meatus with the head in a neutral position and at a 30-degree elevation (Fig. 3). The expected cost of this modified set-up costs between 10 and 20 USD (As opposed to standard devices which cost well over 200USD).

Postoperatively, all patients were managed in the ICU and had continuous monitoring of body temperature, respiratory rate, heart rate, blood pressure, cardiac rhythm, oxygen saturation with an hourly manual recording of the ICP values. Patients with sustained ICP values > 27 cm height for more than 15 min within 1 h during the serial monitoring period had to escalate continuous medical management involving mannitol administration, hyperventilation, or sedation, and therapeutic controlled drainage of CSF up to the point where ICP value was recorded at <27 cm height as a last resort. The outcome assessment employed was 14-day mortality.

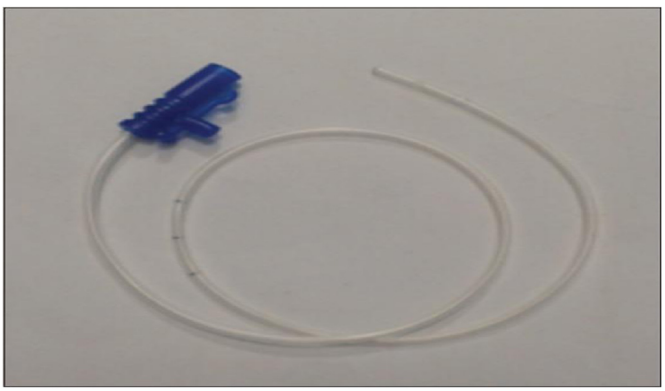

Fig. 1. Size-6 feeding tube.

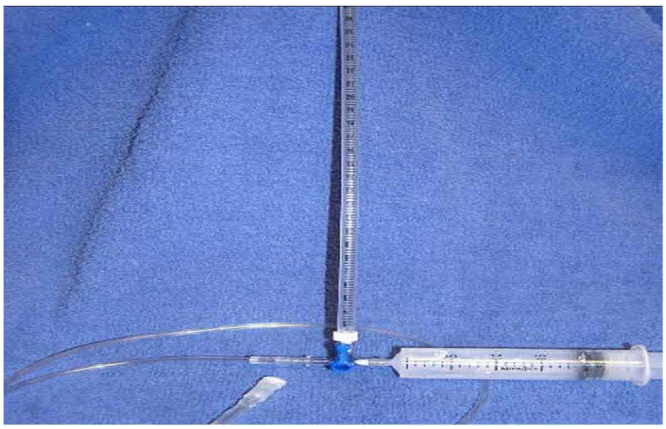

Fig. 2. Size-6 feeding tube and manometer with a 3-way port end.

Fig. 3. Post-operative setup; pressure height is seen with a red top indicator within the chamber.

2.5. Statistical analysis

Statistical analysis was carried out using SPSS version 22 Continuous variables were represented with mean and standard deviation, while categorical variables were described with absolute count with percentages. A univariate model involving $\chi 2$ (or fisher's exact test where indicated) for dichotomous categorical variables was used to test the different categories (ICP-monitored vs non-ICP-monitored) against the outcomes (detection of raised ICP and death at 14 days). Quantitative variables between both groups were compared with the independent samples T-test, while those not normally distributed were compared with the Mann-Whitney *U* test. The paired sample T-test was used for the pre and post-intervention data, while the non-parametric variant (Wilcoxon signed rank test) was used when the sample was not normally distributed. A P-value of <0.05 was considered statistically significant with a 95% confidence interval (CI).

3. Results

The study involved 54 adult patients with severe TBI requiring operative intervention, 25 of which had ICP monitoring using an improvised method. Overall, the age of the study participants ranged between 16 and 80 years. The mean age was 43.0 (±17.3) (Table 1).

Table 1
Age and gender.

Variable	Frequency (%)		
	ICP-Monitored	Non-ICP Monitored	Overall
	n = 25	n = 29	n = 54
Age (year)			
16–30	7 (28.0)	10 (34.5)	17 (31.5)
31–45	8 (32.0)	9 (31.0)	17 (31.5)
46–60	5 (20.0)	6 (20.7)	11 (20.5)
≥61	5 (20.0)	4 (13.8)	9 (16.7)
Mean age	**43.0 ± 17.3**	**40.7 ± 16.2**	**41.7 ± 16.6**
Sex			
Male	19 (76.0)	21 (72.4)	40 (74.1)
Female	6 (24.0)	8 (27.6)	14 (25.9)

The CT scan abnormalities in the identified patients are seen in Fig. 4.

3.1. Intracranial pressure measurements

The ICP reading was measured in centimetres of H_20. For this study, readings 27 cm of H_20 (equivalent to 20 mmHg) were classed as raised ICP. A target ICP of less than 20 mm Hg (27 cm H_20) was defined as normal (Cooper et al., 2011). 84% of the 25 patients who had ICP monitoring had values above 27 cm H_20 within the 72 h of observation (mean ICP 29.4 (±8.1)). The values are seen in Table 2.

In the ICP-monitored group (Also referred to as the invasively assessed), raised ICP was detected more than the clinically assessed group (84% vs 12% p= <0.001) (Table 3).

3.2. Outcome assessment

Overall, the 14-day mortality rate observed was 22.2%. There was a 3-time higher mortality rate among the non-ICP-monitored participants (31%) compared to the ICP-monitored participants (12%). The assessments are seen in Table 4.

4. Discussion

The aim of ICP monitoring in TBI following operative intervention is to allow early detection of secondary intracranial hypertension and to guide therapies that limit this occurrence. This study shows the efficacy of a relatively inexpensive device, providing objective data for timely intervention in reducing elevated ICP. This preliminary study shows a 3-time higher mortality rate among the non-ICP monitored participants (31%) compared to the ICP-monitored participants (12%), although this did not reach statistical significance due to the small sample size. This is likely because of our improvised device's early detection and management of the elevated ICP. Furthermore, the device effectively detected raised ICP levels compared to clinical assessment alone (84% vs 12% p= <0.001).

The management of severe TBI globally, particularly in developed regions, has shown improvements in available facilities due to available resources and technological advances (Patel et al., 2002; Tisdall and Smith, 2007; Roberts et al., 2004). LMICs, however, have limited resources available for health care. Locally, the availability of modern neurophysiologic and structural devices needed for TBI management can be improved. Local neurosurgeons often depend only on conventional computer tomography imaging and clinical parameters in managing patients with raised ICP in severe TBI. This undoubtedly contributes to the much higher case fatality rates recorded in underresourced settings. With this modified device, however, ICP monitoring can now be done at little to no cost where indicated. However, more single and multi-centre studies are needed to validate the findings and confirm their efficacy.

Despite our study, it has limitations. As a preliminary study, our patient population was small and super selective; however, the changes

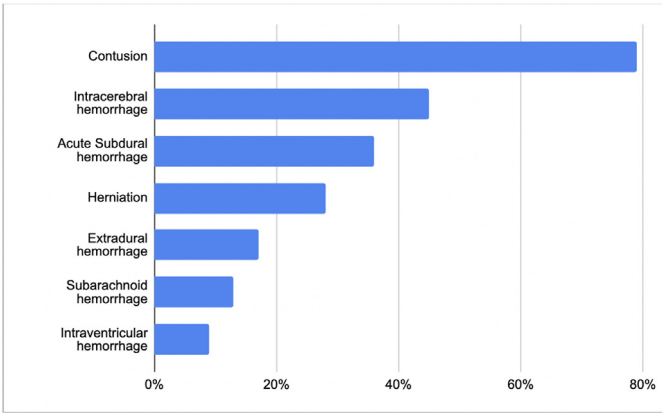

Fig. 4. CT scan abnormalities in study participants
34 patients had primary decompressive craniectomy with/without evacuation of the mass lesion, while 20 patients had craniotomy with evacuation of the mass lesion.

Table 2
Mean ICP values.

ICP (cm of H_20)	Frequency (%) n = 25	
	Within 72 h postoperatively	End of 72 h postoperatively
≤27 (Normal)	4 (16.0)	25 (100)
>27 (Raised)	21 (84.0)	0 (0)
Mean ICP	29.4 ± 8.1	10.1 ± 3.7

Table 3
Comparison of invasively assessed and clinically assessed ICP.

Raised ICP (>27 cm H_20)	Frequency (%) n = 25	
	Invasively Assessed	Clinically Assessed
Detected	21 (84.0)	3 (12.0)
Not detected	4 (16.0)	22 (88.0)

$\chi^2 = 25.962$; df = 1; p-value <0.001; fisher's exact p = 0.000.

Table 4
Overall mortality.

Death within/at 14 days	Frequency (%)		
	ICP-Monitored	Non-ICP Monitored	Overall
	n = 25	n = 29	n = 54
Yes	3 (12.0)	9 (31.0)	12 (22.2)
No	22 (88.0)	20 (69.0)	42 (77.8)

$\chi^2 = 2.814$; df = 1; p-value = 0.093.

observed are likely to apply to similar patient populations. Without any image guidance, the ventricular catheter is inserted free hand, which can result in missed cannulation. This was encountered in eight patients and resulted in multiple attempts before success. In addition, the manometer in our improvised study is cut off at 34 cm, so pressures higher than 34 cm of H_2O cannot be accurately measured. Practically, since the clinical upper limit is 20 cm, it doesn't affect the intervention. We could not compare these improvised devices to standardised devices because of the cost of the device. However, as this is a preliminary study, further studies will aim to improve on all of these limitations.

5. Conclusion

This preliminary study has shown that this modified ICP monitoring system is a relatively feasible alternative for diagnosing and treating elevated ICP in severe TBI in resource-constrained environments.

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Author contributions

J.U- Conception, and design of the study, acquisition, and analysis of data, writing - methods and results, visualization, validation, review, editing and approval. D.A- Conception, and design of the study, acquisition, and analysis of data, writing - methods and results, visualization, validation, review, editing and approval. O.B- Conception, and design of the study, acquisition, and analysis of data, writing - methods and results, visualization, validation, review, editing and approval. O.O- Conception, and design of the study, acquisition, and analysis of data, writing - methods and results, visualization, validation, review, editing and approval.

Declaration of competing interest

The authors declare that they have no competing interests. All authors have approved the final manuscript for submission.

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