Electronic Medical Record Validation: Exploring the Reliability of Intracranial Pressure Data Abstracted From the Electronic Medical Record–Pilot

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Background and Purpose: Intracranial pressure (ICP) monitoring is crucial to decision making for neurologically injured patients, yet measurement of ICP varies greatly among practitioners. Methods: Unblinded, nonrandomized, observational pilot study comparing ICP values collected using pen and paper (P&P), electronic medical record (EMR), and video data with continuous data acquisition (CDA) technology. Results: ICP values did not significantly differ between EMR and P&P records, despite an average of 16 minutes difference in reporting times. ICP values varied significantly when comparing CDA data to EMR or paper. Conclusion: The results of this pilot study put in to question the validity of ICP values that are recorded in the medical record, which has implications for patient care and research.

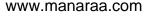
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A comprehensive treatment aimed to reduce or prevent secondary brain injury. ICP values are measured and dutifully documented by nurses in intensive care units (ICUs) and neurocritical care units (NCCUs) across the globe (Badri et al., 2012; Chesnut et al., 2012; Helbok et al., 2012; Lou et al., 2012; Ugras & Aksoy, 2012). For researchers, exploring acute traumatic brain injury (TBI), stroke, neoplasm, and cerebral edema, ICP values are reported both as an independent and as a dependent variable (Helbok, Olson, Le Roux, & Vespa, 2014; Sheth et al., 2013; Szabo, Grap, Munro, Starkweather, & Merchant, 2014; van Veelen et al., 2013; Wang et al., 2013). However, despite the ubiquitous nature of ICP values being measured, documented, and reported in both clinical care and clinical research, there is no universal standard for how ICP is measured or recorded (Olson, Batjer, Abdulkadir, & Hall, 2014; Olson et al., 2013). The specific aim of this study was to provide pilot data for a comparison of the reliability of ICP data sampled using three recording methods: (a) pen and paper (P&P), (b) electronic medical records (EMR), and (c) continuous data acquisition (CDA).

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BACKGROUND

The validity and precision of ICP data collection and its standardization have substantial implications for research as well as for clinical care. Although ICP is referenced as a variable in more than 7,246 peer-reviewed articles in the last 10 years, nearly every aspect of ICP monitoring is subject to ongoing debate (Amato et al., 2011; Bell, 2009; Chesnut, 2013; Chesnut et al., 2012; Hickey, Olson, & Turner, 2009; Olson, Thoyre, Bennett, Stoner, & Graffagnino, 2009; Smith, 2008; Wolfe & Torbey, 2009). ICP values have been recorded using a P&P, EMR, and CDA methods (Amato et al., 2011; Chesnut et al., 2012; Hickey et al., 2009; Olson et al., 2013; Roth et al., 2013; Sheth et al., 2013). Often, the method is not fully described (Scholz et al., 1994; vanVeelen et al., 2013). Computerized documentation is fast replacing P&P. In parallel, data collection is becoming increasingly automated, yet the accuracy of these electronically recorded data compared to the historical standard of recording ICP values has not been evaluated.

The most recent documentation for standardized recording of ICP was last reported in 1991 (Marmarou et al., 1991). This standard specifically advocates against computergenerated values and supports that ICP should be recorded once per hour, by a nurse, using P&P. The rationale for this standard was based on data wherein 17% of electronically recorded values differed by at least 6 mmHg from nurse-recorded values. This discrepancy is likely caused by combination of the high degree of variance in ICP over a short time and how values are adjudicated (Marmarou et al., 1991).

In 1991, when nurses recorded ICP values, they were required to adjudicate, which ICP value should be recorded, a process that was declared provided a "good estimate" of the ICP (Marmarou et al., 1991). The variables accounted for in nurse adjudication are not described. Twenty-four years later, computer technology has advanced considerably and ICU nurses rarely record ICP using P&P. Furthermore, we have entered the era of EMR and CDA software. These technologies enable the auto-population of ICP values into an EMR. Although this has the potential advantage of delegating rote tasks to technology, there is no standardization of the process or validated method for recording longitudinal ICP data from electronic sources.

CDA software leverages technological advances in computer processing and storage to collect and analyze livestream data such as heart rate, blood pressure, and ICP (Park, Kaffashi, Loparo, & Jacono, 2013; Sivaganesan, Manley, & Huang, 2014). Traditional bedside monitors that interact with the EMR typically can provide a maximum sampling frequency of once-per-minute. Even then, the nurse or research must verify each data element prior to that element being available for analysis. In contrast, the CDA sampling rate can be set by the investigator (typically once every 6 seconds) and the data is automatically stored in a format that can be exported directly into analysis software.

The purpose of this pilot study was to explore a novel methodology with the potential to improve our understanding of the reliability and validity of various methods of measuring and recording ICP values in the era of EMRs and CDA. Recent advances in data capture, storage, retrieval, and interpretation provide an exciting opportunity to use video recordings to compare ICP measurement methods. There are a few absolutes that are required for measuring ICP. First, when an external ventricular drain (EVD) is used, the stopcock, which connects the EVD to a pressure transducer must be positioned so that there is a continuous column of fluid from the ventricle to the transducer. Second, the transducer must be calibrated (i.e., "zeroed") and positioned level with the external auditory meatus which approximates the level of the foramen of Monro (American Association of Neurosciene



Nurses, 2010). Commercially available software now exists that can be used to score video-linked CDA data and ensure that the two standard requisites (stopcock positioning and transducer level) for measuring ICP are met.

METHODS

This is an unblinded, nonrandomized, observational pilot study approved by the university's institutional review board to collect video recordings, EMR, P&P, and CDA data from patients admitted to the NCCU who had an ICP monitoring device (EVD or intracranial bolt) at the time of enrollment. Nurses who provided care to patients with ICP monitoring were also consented because their behaviors and measurements were recorded. Nonnursing staff and family members were made aware that video recording was occurring in the patient room by posting a sign on the door to the room.

PARTICIPANTS

Nurses who were employees of the university hospital and assigned to work in the NCCU were considered eligible for the study and were approached for consent. Student nurses and those nurses who had worked fewer than 90 days (still in the orientation phase) were excluded. Patients with an existing EVD used to monitor ICP prior to enrollment were considered eligible. Patients with an EVD solely to manage obstructive hydrocephalus without ICP monitoring, patients who were prisoners, and patients under age 18 years were excluded.

DATA COLLECTION

ICP measurements were obtained for 24 consecutive hours from each of 11 patients enrolled in the study. No changes were made to the plan of care, and nurses and physicians continued to provide the normal standard of care. After consent was obtained, the study team connected a Component Neuromonitoring System (CNS) to the bedside telemetry monitoring system (GE Solar 8000i or Philips IntelliVue). This provided CDA of ICP values (see Figure 1). Next, a video camera attached to the CNS was turned on and positioned to record the position of the stopcock and relative level of the transducer (Figure 2). The CNS provides a singular time-stamp for both the videotape and CDA data. The 24-hour study period began when the CNS and video camera were turned on. Nurses continued to provide care as they normally would; this included positioning the stopcock to drain cerebrospinal fluid (CSF) or to monitor ICP, and to relevel the transducer when the patient was repositioned (or moved themselves) in bed.

For this study, ICP values were documented in three ways. First, nurses documented using P&P. Nurses measured ICP directly by observing the ICP waveform and associated ICP values, documenting the time and the value that reflected the ICP via P&P. Second, nurses documented ICP in the EMR. Nurses logged in to the EMR and either accepted the auto-populated ICP value(s) or they altered those values. All entries were time-stamped in the EMR. Third, research staff documented ICP values using a combination of CDA and video matching.



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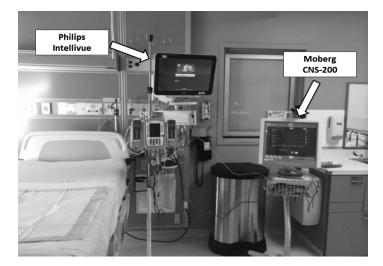


Figure 1. Moberg CNS-200 connected to Philips IntelliVue in intensive care unit patient room.

The CDA and video ICP values were obtained after the study patient was discharged from the study. Data (video and CDA data) were downloaded from the CNS and linked into a single electronic file using commercially available open source software (MEncoder; MPlayer). This file was then uploaded into Observer XT (Noldus) where the video could be viewed time-stamped to CDA data (ICP values). The video was scored by either the clinical research manager or the neurocritical care nurse. The video was scored for items, stopcock position and transducer level. First, the stopcock was scored as "open" if it was set to drain CSF, or scored as "closed" if the stopcock was set to monitor ICP. Second, the transducer level was scored as "level" if the EVD transducer was approximately level to the foramen of Monro, and scored as "not level" for all other conditions. The ICP was documented by the research staff as the average of the ICP values, sampled once every 6 seconds, obtained over a 30-second period where both conditions (stopcock closed and transducer level) were met. If there was not a full 30-second period, the ICP was documented as the average of all ICP values available during the period when both conditions were met.



Figure 2. Stopcock and relative level of transducer.



RESULTS

Data were obtained from 11 patients with ICP monitoring and the 26 nurses who were assigned to provide care to these patients. Patients mean age was 50.7 years, six (54.4%) were female, and eight (72.7%) were White (two Black, and one not declared). Patient diagnoses included subarachnoid hemorrhage (six), intracranial hemorrhage (two), neoplasm (two), and one patient with cerebral edema following ischemic stroke. Nurses were primarily baccalaureate prepared (n = 22, 84.6%) with a mean of 8.3 (SD = 9.8) years of nursing experience and 7.5 (SD = 1.7) years of experience in critical care.

The time at which values were obtained and recorded was examined by comparing the written time (P&P), the EMR time and the time at which an adjudicated CDA and EMR value could be obtained. There was a clinically significant difference when ICP values were documented. The mean difference between when ICP was documented using P&P and EMR was 8.6 minutes (SD = 12.6), the mean difference between P&P and CDA was 18.5 minutes (SD = 13.2), and the mean difference between EMR and CDA 22.0 minutes (SD = 13.4).

Intermethod reliability was first assessed with paired *t* test (Figure 3). ICP values documented using P&P were similar to those documented in the EMR (p = .93) but significantly different from those documented by CDA and video (p < .001). Similarly, ICP values documented in the EMR are significantly different from those documented by CDA+video (p < .001). A correlation matrix (Pearson product-moment correlation) was then developed for CDA and video with P&P (r = 0.66, p < .001), CDA and video with EMR (r = 0.56, p < .001), and for P&P with EMR (r = 0.90, p < .001) and an average inter-item correlation of .71 (Campbell & Fiske, 1959). Finally, Cronbach's alpha was computed to examine the relationship of the entire cohort with P&P (Cronbach's alpha = .88), EMR (Cronbach's alpha = .81), and CDA and video (Cronbach's alpha = .61).

Using the EMR and video, there were 346 observable events when the EVD was closed. Of these, the EVD was closed for a mean of 317 seconds (SD = 45.7, median

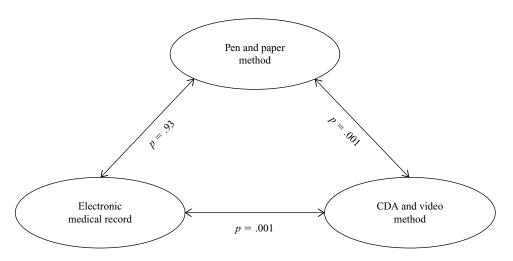


Figure 3. Paired t test for three methods of measurement. CDA = continuous data acquisition.



26.6 seconds). To measure ICP, the EVD was observed closed 165 times for a mean of 114.2 seconds (SD = 28.2, median = 23.8). To calibrate (zero or level) the transducer, the EVD was closed 41 times for a mean of 248.3 seconds (SD = 148.1, median = 13 seconds). Specifically to provide patient care, the EVD was closed 45 times for a mean of 241.2 seconds (SD = 50.0, median = 60 seconds). There were 44 observations where the video of the stopcock was blocked and it could not be determined if the stopcock was open or closed. There was no clear indication for 95 observed events of EVD closure (mean = 734.9, SD = 135, median = 28.5).

DISCUSSION

The aim of this pilot study was to establish the use of videotaping as a potential method of examining standardization that improves the reliability and validity of ICP measurements. The results demonstrate a clear ability to score periods during which the transducer is level with the external auditory meatus, and during which the stopcock is positioned to obtain a recording (closed). The data are rich enough, even in this relatively small sample, that comparisons between recording methods demonstrated clinically and statistically significant differences in ICP measures. This provides further support of the need to determine a consistently reliable method of measuring this critical value.

The finding that ICP is often recorded with only minimal periods of EVD closure deserves confirmation in a future study. The nursing staff in this ICU provided anecdotal evidence prior to the study that the EVD stopcock was typically closed for roughly 5 minutes when obtaining an ICP measurement. In this study, the EVD was closed for an average of less than 2 minutes when obtaining an ICP value. This is a major finding that could have highly significant implications. In an international practice survey, Olson et al. (2014) found that the most neurocritical care physicians (74.9%) would wait longer than 2 minutes after closing a stopcock to obtain an ICP value. Hence, recording values at nonstandardized times after closure is expected to result in highly variable and inaccurate ICP readings. Further research should focus on determining a standard or optimal time for which the stopcock should be closed.

The correlation between P&P documentation and EMR documentation was, as expected, greater than that of CDA to either P&P or EMR. However, one would expect that the correlation would be nearly perfect given that the nurse documenting using P&P is the same person documenting the same value at the same time using EMR. The lack of agreement further supports two key concepts. First, the ability of this methodology to find and score these differences supports the robustness of the methods. Second, the findings that P&P, EMR, and CDA have very different results supports the need for continued efforts to determine a best-practice method for measuring and recording ICP.

The difference in documentation times for P&P, EMR, and CDA is an unexpected finding. Intuitively, one would expect that because the stopcock must be closed to obtain an ICP reading, the times would be nearly perfectly matched. However, the variation was significantly different, suggesting that the staff closed the EVD at one time point (generating a CDA ICP value), documented the reading on P&P at a different time point, and then documented an EMR ICP value at a third time point. This may be explained by the fact that most ICP reading in the EMR were at the top of an hour (e.g., 2:00 p.m.), yet rarely was the EVD stopcock closed at exactly the top of an hour. Hypothetically, this occurs because the nurse is busy with other tasks; however, there are no data available to test this hypothesis.



Because ICP changes very quickly over a short time, the difference in documentation time could be clinically relevant and deserve additional research.

LIMITATIONS

Limitations encountered during the progress of the study included visibility of the EVD stopcock, parameters of CDA storage, and differing time stamps between video recordings and CDA values. Although the video recordings provided valuable confirmatory information in relation to incoming ICP values, nurses and other health care providers would occasionally reposition the video camera, thus inadvertently obscuring the sightline to the EVD stopcock or removing it from view completely. Without the visualization of the position of the stopcock, the ICP values could not be used. Also during nighttime hours, low lighting or lack of light precluded visual confirmation of the EVD stopcock despite correct video camera positioning. Furthermore, the CDA input recorded the average of ICP values every 6 seconds. This protocol sometimes would "dampen" sharp spikes in ICP that occur with daily care of the patient. It was discovered that a delay existed between the video recordings and CDA recordings. Despite time stamps that were added to match the CDA with video data, there may still be a slight delay that could not be accounted for in the data analysis. It would be beneficial to conduct a follow-up study that can further explore ways in which to render the earlier mentioned limitations.

The 44 observations wherein the positioning of the video camera relative to the EVD stopcock deserves attention in future studies. In this study, the CNS monitor and camera were attached to a single mobile stand (on wheels). It was noted that several staff nurses moved the CNS monitor and video camera to facilitate patient care. This is, of course, entirely appropriate as nurses were instructed to provide care in a normal manner. The use of a wide-angle lens with the monitor and camera positioned well away from the patient may reduce the number of times when the video is obscured. Finally, the differences in documentation times may or may not be clinically relevant. This study was neither designed nor powered to detect this difference and future research should strive to address this question.

CONCLUSION

ICP has been shown to be an important part of clinical care and a major indicator for acute research outcomes, yet there continues to be disparity in the way ICP is measured. Although this study sheds light on the differences in reporting of ICP, more research is needed via video-enhanced scoring of CDA data as a possible best method for accurately recording ICP.

The results from this study will have profound implications for critical care research and the impact is not dependent on any one given result. Regardless of which method is found to provide the highest quality, reliable ICP data, the standard will be set. Furthermore, knowing the benefits and limitations of each method (Aim 1) allows researchers and clinicians to be more informed decision makers. ICP monitoring is one of the top eight research priorities for neurocritical care nursing, (Olson et al., 2011) but there is significant practice variation and no standard guiding researchers toward best practice for recording ICP (Bennett, Riva-Cambrin, Keenan, Korgenski, & Bratton, 2012; Olson et al., 2013).



The heterogeneity associated with recording ICP limits the generalizability of findings from any one institution and limits the ability to conduct multicenter trials. The results from this study are an essential first step toward broad collaboration.

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