Integrating Quantitative Pupillometry Into Regular Care in a Neurotrauma Intensive Care Unit



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ABSTRAC1

In the setting of acute traumatic brain injury (TBI), an abnormal pupil assessment may suggest a worsening intracranial lesion. Early detection of pupillary changes may expedite emergent care to improve outcomes. Automated, handheld pupillometers have been commercially available for 20 years, and several studies suggest that their use may facilitate early recognition of worsening injury and intracranial hypertension. The use of pupillometry as a bedside tool in the routine care of patients with severe TBI (Glasgow Coma Scale score ≤ 8) has not been described. We performed a quality improvement project to implement routine use of quantitative pupillometry in our neurotrauma intensive care unit. Nursing staff were trained on device use and the project's aims in a 30-minute in-service session. Nurses caring for severe TBI patients completed standard pupil assessments using (a) a flashlight and (b) a pupillometer to quantify pupil size and reactivity (Neurological Pupil index) every hour. Abnormal results were reported to on-call providers. We administered surveys to evaluate knowledge, practical use of the pupillometer data, and satisfaction with the device every 3 months. Data were available for 22 nurses at 4 separate time points. Staff were positive about their ability to use and understand the device ($\mu = 8.7$ and 9.1, respectively, on a 10-point scale) and reported that it added value to patient care and critical decision-making. Use of automated pupillometry is acceptable to nursing staff in a neurotrauma intensive care unit, and staff believed that pupillometry results enhanced clinical decision-making.

Keywords: critical care, intensive care unit (ICU), neurological pupil index (NPi), neurotrauma, nursing, pupillometer, technology, traumatic brain injury (TBI)

raumatic brain injury (TBI) is common. In 2010, there were 2.5 million emergency department visits, hospital admissions, or deaths due to TBI. Each year, TBI costs the nation upward of \$76 billion.^{1,2} The Brain Trauma Foundation's (BTF's)

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"Guidelines for the Management of Severe Traumatic Brain Injury" is a living document containing evidencebased management recommendations that set the benchmark for high-quality TBI care.³ Because even 1 incidence of elevated intracranial pressure (ICP) can lead to poorer outcomes, the BTF recommends close ICP monitoring.³ Additionally, adherence with BTF guidelines is associated with improved outcomes.⁴ Intracranial pressure monitoring is generally performed invasively via ventriculostomy or an intraparenchymal pressure catheter, and clinically, these measurements are interpreted in the context of frequent neurological assessments.

Bedside assessment of pupil size, shape, reactivity, and relative symmetry is a cornerstone of the neurological examination of the brain-injured patient. Gross pupillary assessment holds the promise of bedside detection of expanding or emerging intracranial lesions that might cause downward pressure on the brainstem. Multiple studies have found a direct correlation between abnormal pupil assessments in severely brain-injured patients and poor outcomes for those patients.^{5–9} Interventions that restore pupillary symmetry and reactivity in as short a time as possible lead to better outcomes.⁹ Although this correlation

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is clearly not because irregular pupils are lethal in and of themselves, the abnormal response is a figurative, as well as literal, window to the underlying pathology and the dangerously elevated intracranial pressures, decreased blood flow, and irreversibly injured brain tissue that are a result of that pathology. Unfortunately, in practice, pupil assessment is often completed by multiple critical care team members independently of each other, and individuals are not able to accurately estimate pupil size.^{10–14} Communication of key data is hampered because, although intrarater reliability of subjective pupillary assessment is high, the reliability that a single examiner will make consistent judgments of pupil size, interrater reliability, and agreement between different examiners is low.^{15,16}

Automated, handheld pupillometers have been commercially available for more than 20 years, but penetration into bedside practice has been low. Previous studies have validated this technology and demonstrated improved reproducibility compared with provider estimation of pupil size.^{17–19} Newer handheld devices not only measure pupil size but also quantify reactivity and provide additional information such as: minimum and maximum pupil sizes, the percent change in constriction, the latency of constriction, and the constriction and dilation velocities are combined using a proprietary algorithm to derive a final Neurological Pupil index (NPi) value that ranges from 0 to 5. An NPi of less than 3 is abnormal and corresponds to what most experienced examiners would describe as a sluggish or absent response to light.²⁰ Previous studies have suggested that NPi might predict subsequent increases in ICP.^{20,21} There is a current and growing interest in the neuroscience community in increasing the rigor of quantitative pupillometry use in research and clinical practice.²²

The purpose of this quality improvement project was to augment the evidence-based, severe TBI protocol already in place in a neurotrauma intensive care unit (NTICU) by using the pupillometer for regular pupil assessments to establish whether the pupillometer could be successfully integrated into the established nursing workflow. In this project, quantitative pupillometry was successfully integrated into routine clinical practice in our NTICU, and we report on an initiative for nursing education and our results in terms of knowledge retention and provider satisfaction.

Methods

We collected all data from a single NTICU at a level I trauma center in western Pennsylvania. Our NTICU is a 10-bed trauma intensive care unit (ICU) specializing in the care of severe TBI and spinal cord injuries. A

The results suggest that new technology may take time for acceptance into routine practice.

total of 22 registered nurses (RNs) staff the NTICU and were included in this project. The University of Pittsburgh Medical Center (Pittsburgh, PA) Quality Improvement Committee and the University of Pittsburgh Medical Center (Pittsburgh, PA) Evidence-Based Practice Committee approved all aspects of this study.

A protocol for routine pupillometer use was developed and distributed to NTICU staff by email and was also displayed on a bulletin board in the NTICU. Every patient admitted with severe TBI received a new eye shield, and bedside nurses completed pupillometer assessments every 1 hour immediately after a standard manual pupil assessment was performed. Additionally, pupil assessments were performed at the time of any new ICP elevation or other clinically significant changes in patient condition. Bedside nurses recorded the results of both their qualitative and quantitative pupillary assessments both on a paper flow sheet and in the electronic medical record. They also communicated any new abnormal findings to both critical care and neurosurgical providers.

For training, a single study author (M.A.) provided four 30-minute in-servicing sessions to the NTICU bedside nursing staff and nursing supervisors, with 100% overall staff participation. Throughout the project, when new nurses were hired onto the unit, they were inserviced on the project by the study principal investigator and their RN preceptor. We also provided a brief introduction to the project to the neurosurgical residents during one of their educational sessions and provided email background information to the critical care attendings, advanced practice providers, and rotating trainees.

A standardized 8-question knowledge assessment was administered to the nursing staff after the inservice session (Table 1). We designed these questions to test whether providers knew the aims and purpose of the project, the evidence supporting pupillometer use, and what the NPi measures. Three random questions were repeated from this list via a paper survey every 3 to 4 months to test knowledge retention; only 1 question was administered more than once. At these intervals, we also asked providers 5 questions pertaining to their satisfaction with the

#	Question	Possible Answers	% Correct Initially	% Correc Subsequent
1	What type of patient will the pupillometer	A. Any neuro patient	90.5	100
	be used for in this project?	B. TBI protocol patient		
		C. SAH patient		
		D. B and C		
2	How often will you take a pupillometer	A. Q 1 h	57.1	54.5
	measurement?	B. Q 2 h		
		C. Whenever I check pupillary response manually		
		D. Q shift		
3	When calling neurosurgery and then CCM	A. True	100	95.5
	with an abnormal neurological examination, should both the manual pupil examination and the NPi be reported?	B. False		
ŀ	If a unilateral lesion was causing downward	A. NPi > 3	81	90
	pressure on the brain stem, you would	B. NPi ≤ 3		
	expect?	C. Unilateral abnormal pupil response		
		D. Both B and C		
	The Neurological Pupil index (NPi)	A. Symmetry	52.4	78.6
	measures?	B. Shape		
		C. Speed of constriction		
		D. A and B		
		E. B and C		
	A known benefit of pupillometer	A. Speed of examination	100	100
	measurements over manual pupil checks is?	B. Precision of measurements		
		C. Availability of equipment		
	A possible benefit of pupillometer	A. Prediction of future ICP spikes	100	100
	measurements over manual checks is?	B. Quicker assessments		
	The individual eyepiece should be thrown	A. Every pupil check	100	100
	away after?	B. Every shift		
		C. Every day		
		D. Every patient		

TABLE 1. Knowledge Questions and Percent Answered Correctly, Initially and Subsequently

Note. This table shows nursing survey knowledge questions and percentage of nurses answering correctly after the initial in-service compared with the percentage of nurses answering correctly in the subsequent surveys.

device (Table 2). After each survey, an email was sent to the nursing staff to reinforce the correct answers from the knowledge questions. Finally, in a cohort of consecutive subjects with severe TBI, defined as a Glasgow Coma Score of 8 or less, hourly pupil size and reactivity measured by pupillometry and with standard flashlight assessment were recorded.

Descriptive statistics were used to summarize overall results. A 2-sample Wilcoxon rank sum test was used to evaluate improvement in satisfaction during the course of the project for each satisfaction question asked, and a test of proportions was used to analyze changes in overall knowledge retention as evidenced by the percentage of nurses who answered each question correctly at the initial in-servicing and then again during the project.

Results

We collected nursing satisfaction surveys in December 2015, March 2016, and August 2016 during the project

TABLE 2. Nursing Satisfaction (10-Point Scale)	Satisfa	ction (10-	Point Scal	e)									
		Dec 15 $(n = 21)$	21)		Mar 16 $(n = 20)$	20)		Aug 16 $(n = 22)$	22)		Mar 17 $(n = 19)$	19)	
	n.	SD	Mode	n.	SD	Mode	ц	SD	Mode	'n	SD	Mode	Ρ
I understand the data from the pupillometer.	9.1	1.12	6	8.9	1.35	10	9.2	1.26	10	9.5	1.15	10	.35
I think the pupillometer is a useful tool in the NTICU.	8.9	1.41	10	8.1	2.29	6	8.9	1.27	6	8.4	2.54	10	.83
The pupillometer is easy to use.	8.7	2.3	10	8.7	2.09	10	9.2	1.08	10	9.6	0.7	10	.78
Data from the pupillometer guide my decision-making.		2.17		7.3	2.79	10	7.5	2.23	6	7.2	2.79	10	.24
I prefer to use the pupillometer over the flashlight.	4.6	2.71	4	4.3	2.66	4	6.5	2.99	10/5	5.8	3.3	10	.02
Abbreviation: μ, weighted mean.	Ľ												

and a poststudy survey in March 2017. Twenty-two surveys were collected at baseline, with 19 to 22 surveys submitted at follow-up time points. Overall, measures of self-assessed understanding were high throughout the survey periods (Table 2). Satisfaction with ease of device use and usefulness in practice were also high throughout the survey periods. Usefulness of the device in guiding decision-making was scored moderately at baseline and during the study, although this was likely driven by low scores from a few participants on this item, and only improved to a high average score at the end of the study period. A minority of nurses indicated that they preferred to use pupillometry compared with a conventional flashlight, although this also seemed to improve over time.

There was no change in self-assessed understanding or satisfaction over time, except with regard to whether nurses preferred to perform pupil assessments with a flashlight or pupillometer. For this final question, the average response at baseline was 4.6 on a 10-point scale indicating a below-average agreement with the statement. For the August 2016 and March 2017 surveys, the average increased to 6.5 and 5.8, respectively, with bimodal and increased mode in the latter 2 survey periods. A Wilcoxon rank sum test showed that preference for using the pupillometer over the flashlight increased significantly from the beginning of the project until the end of the project (z =-2.367, P = .0179) and that the preference persisted, if not increased, 6 months after the conclusion of the project.

The survey tested the knowledge of neurologic implications of increased ICP, the study protocol, the pupillometer device use and benefits, and the reporting of pupillometer findings (Table 1). At baseline (after in-servicing), overall knowledge regarding both implications for the neurologic population and use of the device was already high. There were lower scores on responses to questions 2 and 3, relating to study protocol regarding device use (and, specifically, frequency of pupil assessments) and clinical use of pupillometer findings (reporting to advanced practice providers), and question 5, regarding definition of the NPi. There was an overall nonsignificant trend toward increased knowledge both overall and for each question.

Discussion

These results suggest that new technology may take time for acceptance into routine practice in an ICU setting and the acceptance of new technology most likely hinges on a variety of factors. Regular bedside conditions, especially in an ICU, are not stable, and often, idealized methods for patient care, such as new

instruments and new protocols, are transmuted or even ignored in favor of patient care in a critical moment. The critical thinking skills and judgment of the bedside nurse will always take precedence over a new device such as the pupillometer, and so, it is important to introduce and integrate new technology thoroughly and to adjust goals based on nursing feedback. This 13-month study showed that the RNs in this NTICU could understand and use the pupillometer regularly showing that use of the pupillometer in the NTICU was feasible and practical. Satisfaction data showed that nurses believed it was an effective tool with clinical implications in the NTICU and yet, by the end of the study period, more than 50% of the nurses did not feel that the pupillometer was the preferred method for pupil assessments. We did not collect data to further explore this change. It may be that inconsistent provider response to abnormal NPi, inconsistency in the results obtained, or persistent opinions about the equivalency of results obtained from the pupillometer versus the standard method could have all been factors in this result.

One model for understanding the process of acceptance and adoption of new tools in healthcare is Rogers' Diffusion of Innovation theory, which outlines the stages of individual acceptance of innovation but, in addition, defines the influential characteristics of a new tool that drive the decision about whether to adopt or reject the innovation. These include relative advantage, compatibility, complexity, trialability, and observability. The RNs in this study agreed that the pupillometer was compatible and easy to understand. There was sufficient time to try the device, acclimate to its use, and integrate it into regular care. Consensus on relative advantage of the pupillometer was not obtained, however, and exploration of observability, or the degree in which the results are observable by others, was not completed.²³

In addition to a precise and reproducible method of quantifying pupil size, additional quantitative measures of reactivity may be clinically important, but the exact nature of the role of NPi or other quantitative measures of reactivity is still unclear. A 2011 multisite study by Chen et al²¹ used the pupillometer in the ICU to complete pupil assessments for severely braininjured patients. they not only did redemonstrate the accuracy of the pupillometer compared with human examiners but also used the NPi to quantify reactivity and tested whether poor NPi values could be correlated to intracranial hypertension. They found that patients with an NPi of 3 or less at any point had consistently higher ICPs than those with "normal" pupil reactivity and that abnormal NPi readings initially appeared, on average, 15.9 hours before peak ICP elevations. This raised the possibility that the NPi could be an early

predictor of intracranial hypertension and built on a previous study by Taylor et al²⁰ that found that a decrease in constriction velocity to less than 0.6 mm/s predicted an increase of ICP greater than 20 within the next 15 to 30 minutes. The possibility of using pupillometry measurements to predict intracranial hypertension, a known factor in poor patient outcomes,^{3,24–26} continues to be a strong focus of clinical research. McNett et al²⁷ recently showed that, in pooled data from 76 patients with 72 hours of hourly pupillometer readings per patient, the ICPs were correlated to both the NPi and the constriction velocity.

In the NTICU, where nurses are highly experienced in evaluating pupil size, symmetry, and reaction using the standard flashlight method, an automated device may add a limited incremental value unless reactivity can be shown to be a quantitatively valuable clinical variable. It is possible that it would have a greater value for nursing and medical providers who have less focused neurological training and experience.

Our study has several limitations. First, because we asked generally whether nurses felt that pupillometry guided their clinical decision-making but did not specifically investigate which data from the device they found informative, we could not determine how bedside clinicians integrated the data into their practice. However, because our focus was integration of the device itself and not the specific measurements provided by the device, this limitation does not detract significantly from our conclusions. Second, the satisfaction and knowledge surveys were anonymous, and so, repeated measurements could not be matched, which not only limited the accuracy of the test of proportions, in the case of the knowledge analysis, but also made it difficult to further analyze the difference between those nurses who preferred the pupillometer and those who would rather use the flashlight method. However, anonymity allowed for greater honesty in answering questions about satisfaction. Finally, because the questions for the satisfaction and knowledge test were generated just before the project, test validation was not completed. Question 2 of the knowledge questions, for example, asked how often the pupillometer examination should be completed. The answer choices were as follows: A, every 1 hour; B, every 2 hours; or C, whenever the standard pupil examination is done. Option C was the correct answer, but this question tapped an underlying confusion about how often to do the pupil examination for TBI protocol patients, especially among newer nurses who were still learning the protocol, and the test questions made the RN choose between 2 possible correct answers. Like college nursing examinations, there was 1 answer that was more correct, but for this survey, the question was likely too complicated for a straightforward assessment of knowledge retention. This was not a critical limitation, however, because we were looking for knowledge retention and a poorly written question did not affect our analysis in any meaningful way.

Conclusion

Overall, the pupil assessment remains an integral part of the complete neurological examination in the setting of severe TBI and other critical brain injuries. We developed and implemented a quality improvement project to pilot the use of the pupillometer in an NTICU during a 13-month period and assessed nursing satisfaction and knowledge retention. We found that using the pupillometer, rather than relying on the standard flashlight pupil assessment, was acceptable to staff in terms of use and ease of use but was not ultimately preferable in the NTICU setting. An additional study to determine whether the NPi or another measurement of reactivity can be used clinically to improve patient care in regular ICU conditions or nonspecialized ICUs should be completed to determine the true use of the automated pupillometer.

For nurses who are already experts in performing a neurological assessment and caring for neurologically, critically ill patients, incorporating a pupillometer into regular bedside care would be simple in both practice and theory. In neurological ICUs, the additional accuracy of the data that can be collected with the pupillometer may shed light on ongoing processes such as intracranial pressure. In nonneurological nursing units, the pupillometer can objectively measure pupil size and symmetry offering increased confidence in the neurological assessment.

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