Pupillary assessment in neuro-ICU: digital penlight versus conventional penlight

Version 1.0 (3 August 2022)

Chief Investigator
Mr. Simon Raby
Consultant in Neurocritical Care and Clinical Director for Major Trauma
John Radcliffe Hospital, Oxford

Synopsis

Study Population	Patients in the neuro-intensive care unit
Intervention	Smartphone pupillary measurement
Study Duration	1 Month
Primary Outcome Measures	Pupillary light response Anisocoria Acceptability of smartphone digital penlight

Objective

To assess the benefit of a smartphone digital penlight for pupillary assessment in neuro-intensive care unit (neuroICU) patients.

Rationale

Current standard of care for patients admitted to the neuroICU includes assessment of the pupillary light reflex using a penlight on a regular basis (often as frequently as hourly). Some units use hardware pupillometers. The pupil diameter is estimated by the examiner without a light stimulus by comparing it to a chart of pupil sizes (often printed on the side of a penlight). Following this, each pupil is assessed for its response to light with the examiner reporting whether the pupil is reactive. These manual assessments are at high risk of inter and intra-observer variability.

A digital pupillometer produces an objective measurement of pupil size and the response to light. There is also potential time-efficiency if the digital data can be automatically synced with the electronic medical record, rather than the results of a conventional penlight being manually typed. Furthermore, comparison of a series of results is easier with a digital measurement device.

A recent National Institute for Health and Care Excellence (NICE) briefing paper addressed pupillometry in ICU.[1] An interesting observation from one of the expert authors was that objective pupillary assessment takes away a burden of responsibility for the nursing staff, which they are aware can influence patient management decisions.

An additional benefit of a digital solution for measuring pupillary response is the significant reduced need for plastic, non-environmentally friendly pen-torches, which often have non-rechargeable or exchangeable batteries.

Design

This study will involve ten smartphones, with the digital penlight software application, being assigned to ten neuroICU beds for one month. Between the day shift hours of 0900 and 1700, when a penlight test is being performed for routine clinical reasons on a patient in one of these beds, an additional set of pupil measurements will be performed using the smartphone digital penlight. The anticipated time for the additional measurements is 90 seconds.

Prior to their first usage of the smartphone digital penlight, a questionnaire will be completed by nurses regarding their current practice of performing pupillary light measurements. At the end of the one month study period, the same nurses will complete a similar questionnaire.

Outcome measures

Pupillary light response
Presence of anisocoria
Questionnaire results

Patient selection

The study will run for one month in neuroICU, using the patients who occupy the ten beds allocated a smartphone.

Inclusion Criteria

- Patients admitted to the neuroICU undergoing pupillary assessment as part of routine care

Exclusion Criteria

- **Complex ocular or facial trauma precluding pupil visualisation**

Sample size and statistical analysis

Given the pilot nature of this study, it is not possible to draw up formal power calculations
Given the pilot nature of this study, it is not possible to draw up formal power calculations

Smartphone Digital Penlight

Commented [SR2R1]: Not sure we need to exclude anyone - maybe for the purposes of the study we need to state that we would not include a patient whose pupils were not accessable - ocular trauma etc. But this is not liekly to practically reduce the inclusion.

Commented [SR3R1]: Other studies have excluded penetratign brain injuries (very rare), and significant ocular trauma (to exclude "peripheral" pupillary changes)

Commented [JN4R1]: OK, makes sense. It will be challenging to get good past ocular histories from these patients, so we could say that those with ocular trauma as part of their reason for admission would be excluded

Pupillary measurement using a smartphone can be considered safe. It involves using the video camera and flashlight from the smartphone. The video of the eye has a duration of approximately 5 seconds, which includes a brief flash of light (akin to taking a single flash photograph). There is minimal risk therefore to the patient.

Smartphone digital penlight assessment will be performed by the nurse looking after the patient. This is the testing sequence for the study;

1. Nurse performs and documents routine pupil measurements using conventional penlight.
2. Nurse opens the Solvemed software application on the allocated smartphone
3. Right eye pupil trace is performed twice
4. Left eye pupil trace is performed twice
5.

Data management

The Chief Investigator will act as custodian for the trial data at each site.

Type of data collected and stored
Solvemed's software as medical device (SaMD) collects 30 – 240 frame-per-second (fps) videos of the eye of an individual (''tested individual'', e.g. patient) i=. In addition, depending on the specific research study requirements and/or engagement terms, the associated relevant information about the tested individual (e.g. demographic, medical, behavioural) information, and the smartphone app metadata can also be collected. The nature and extent of collected data is discussed in detail, and agreed upon prior to the start of data collection, with each collaborator, and – where required – approved by relevant research ethics committees. For this study, at the end of the study period, anonymised data will be gathered from the patient electronic medical record. This data will be the pupillary penlight measurements, relevant physiological parameters (e.g. blood pressure), relevant medical history, and demographic details (age, sex).

Tested individual's privacy
Solvemed collects measurement data, and de-identified, non-personal, non-identifiable information (e.g. demographic, medical, behavioural) about its tested individuals, and thus ensures and protects their privacy. Solvemed neither collects nor stores tested individuals' personal information (identity data), such as their names, surnames, addresses, telephone numbers, email addresses. Instead, a unique ID number is assigned to each tested individual, with Solvemed having no ability to link the ID number with the tested individual's identity. Moreover, to ensure the stored images are devoid of any identifiable information, we apply – to all captured video frames – following the video capture, an image cropping

Commented [SR10R9]: actioned

Commented [JN12R11]: I think we can remove, given the below section

Commented [SR13R11]: done

Commented [MW15R14]: Does the below (Data management) answer this?

Commented [JN16R14]: yes

Commented [MW18R17]: Hopefully now addressed?

Commented [RC19]: We should not be giving such details

Commented [SR20R19]: @radek please delete anything you feel shouldn't be in the submission.

Commented [SR21R19]: @Radek Chrapkiewicz

Commented [JN22R19]: ok

Commented [JN23]: Should we expand on this? @Michal Wlodarski what was the wording we used in the docs for London East?

Commented [MW24R23]: It was minimal:

The Chief Investigator will act as custodian for the trial data at each site. The following guidelines will be strictly adhered to:

Patient data will be anonymised
All anonymised data will be stored on a password protected computers and servers equipped with industry standard encryption.

Commented [MW25R23]: @James Neffendorf How would you expand it?

Commented [JN26R23]: Yes, add in this info

Commented [SR27R23]: @Michal_Wlodarski is this done?

Commented [JN28R23]: Looks to be done

procedure to ensure that only the image of the eye is stored for analysis. The other parts of the image that are not the eye (e.g. the tested individual's face, image background, etc.) are discarded and are not retrievable.

Devices (smartphones) used for data collection
Solvemed captures videos using smartphone cameras. Presently, private smartphones are not used to collect data used by the company. Instead, the company provides its smartphones (smartphones it owns or leases) to collaborators for the duration of the projects. Company smartphones are used solely for purposes connected directly with the objectives of company projects, as discussed in detail and agreed upon with the collaborating parties prior to the start of data collection.

Upload to cloud for secure storage
Following video capture, the video is uploaded onto the company-owned Amazon S3 server storage space (the cloud storage), where the captured videos and any associated data are stored in Amazon SQL databases. The exact time needed to upload a video to the cloud depends on the local network's upload speed and the exact app settings selected by the user, which in turn determine the size of the video file. Prior to the upload, videos may be compressed and analysed with neural networks. To ensure the stored data is secure, company applies an industry-standard Hypertext Transfer Protocol Secure (HTTPS) encryption protocol for all traffic between its smartphones and AWS servers. In addition, company applies suitable company-level policies regarding the access levels and procedures regarding every Amazon AWS component, using appropriate Amazon roles and Amazon policies.

Video analysis and output presentation
Results of video processing and data analysis are displayed to the user (e.g. a physician or researcher) using the smartphone app front-end. No web platform front-end is currently available to Solvemed users (in development). Presented outputs include the videos previously recorded by the user, plots of time traces (change of a variable over measurement time), and relevant extracted numerical parameters.

References

1 NPi-200 for pupillary light reflex in critical care patients. Medtech innovation briefing [MIB235]. National Institute for Health and Care Excellence. 2020