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TRANSORBITAL ULTRASOUND MEASUREMENT OF OPTIC NERVE SHEATH DIAMETER. A NOVEL TECHNIQUE FOR MEASURING INTRA - CRANIAL PRESSURE IN A NEUROSURGICAL INTENSIVE CARE SETUP.

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ABSTRACT **Observations & Results:** In this study 60 patients were enrolled. Mean age of cohort was 40.18 years, with a sex ratio of 1: 1.22 (Male: Female). Mazean pre-operative ONSD value for right eye was 4.82 mm and post-operative ONSD value for right eye was 4.13 mm. Mean pre-operative ONSD value for left eye was 4.86mm and post-operative value was also 4.13mm. Intra class correlation coefficient was > 0.7 for both eyes during pre-as well as post-operative studies suggesting a strong Intra – observer agreement. Mean time taken per patient was 11.48 minutes pre-operatively and 11.67 minutes post-operatively.

Conclusion: This study illustrates the feasibility of non-invasive transorbital ultrasound for assessing optic nerve sheath diameter (ONSD) and to use it for the monitoring of patients in neurology intensive care units for the assessment of raised ICP as a noninvasive tool. The mean value pre-operatively is 4.84mm and suggests raised ICP. Results demonstrate a significant difference between ONSD of patients before and after neurosurgical procedure, and thus support the suggested hypothesis of a relationship between deformability of the ONS and ICP. ONSD measurement on ultrasound yields consistent and acceptable intra - observer variability and repeatability. Further validation of this technique in prospective, blinded studies would be helpful.

Response to Reviewers: Authors feel that review of literature is adequate for the concerned topic due to its very wide implications. Advised changes have been made and appropriate references have been mentioned and highlighted.

KEYWORDS : Raised ICP; intra cranial pressure; optic nerve, papilledema

INTRODUCTION:

Elevation of intracranial pressure (ICP) is a common phenomenon caused by a variety of neurosurgical disorders as brain tumors, intracranial bleeding, infection or head trauma and may lead to life threatening complications. Neuroimaging techniques as computed tomography (CT) and magnetic resonance imaging (MRI) can help to assess raised ICP but have their diagnostic limitations as well and require a potentially harmful patient transport [1] [2]. The gold standard for ICP measurement remain to be invasive intracranial devices: in addition to the need for neurosurgical operation and contraindications (e.g. thrombocytopenia) these methods are associated with certain complications as hemorrhage, infections and shunt technical failure [3]. Changes in the ONSD can be visualized using images from ultrasound, MRI and CT scans. Several studies have demonstrated a strong association between distension of the ONSD and Optic nerve sheath diameter (ONSD) might be an interesting bedside tool for evaluation of these critically ill patients. The optic nerve originates ontogenetically from the central nervous system. It is encased by a dural sheath, with a perineural, subarachnoid space between the nerve and the dural sheath. This perineural space is filled with CSF and is in direct communication with the intracranial subarachnoid space. An increase in ICP results in displacement of CSF along its various pathways. The increase in CSF within the space surrounding the optic nerve results in expansion of the ONS.The suggested cut-off values in these studies range between 4.1 - 5.9 mm and the definition of increased ICP also varies considerably, between 14.7 and 30 mmHg. Several studies investigated the utility of measurements of the ONSD as an indicator for ICP measurement and management [4]. Differing modalities have been used in modern neurosurgical era by various clinicians and surgeons such as Ultrasound as by Bhandari et al, Magnetic resonance imaging by Padayachy LC et al [18] [19]. The primary advantage of using ultrasonogram technology is the low cost and ease ofavailability of the device. Also, patients in neurocritical care setups cannot always be moved around for imaging. However, the main limitations of ultrasound-based ONSD measurements are hyperechoic artefacts, inter-examination variability, small size of the structures and measurements, variation in optic nerve sheath cut-off values and heterogeneity of the patient population [5] [6].

Despite these limitations, ONSD measurement has been described as a useful screening method to detect clinically suspected raised ICP, especially where invasive monitoring is not readily available [7] [8] [9].

AIMS & OBJECTIVES:

- To evaluate efficacy of optic nerve sheath diameter (ONSD) by ultrasound detecting raised intracranial pressure (ICP) in neurosurgical patients of intensive care unit.
- To examine the correlation between individual repeat measurements acquired in the same plane of
- the same eye as an assessment of repeatability of the technique;
- To examine the correlation between mean ONSD measurements by the same observer at different time points as a marker of intra-observer variability;
- To examine correlation between the mean values acquired in each eye.

MATERIAL & METHODS:

The current prospective study was carried out in the Department of Neurosurgery, at BANGUR INSTITUTE OF NEUROSCIENCES & SSKM HOSPITAL, IPGME & R, Kolkata, India, from 2014 – 2017. A total of 60 patients were enrolled in the study. Adult patients admitted in neurosurgical intensive care unit with possible elevated intracranial pressure were evaluated preoperatively just prior to surgery and after 24 hours of operation. 3 measurements were taken for each eye per patient. Patients less than 15 years of age, those with maxilla – facial trauma, orbital edema, previous ocular surgeries were excluded from the study. All evaluations were done by the same surgeon and radiologist.

OBSERVATIONS & RESULTS:

A total of 60 patients were enrolled in the study and were evaluated at the end based on various Demographic and radiological parameters.

In this study, the mean age of the population was 40.18. Amongst the males, the mean was 37.81 years while amongst the females it was 42.12 years. The cohort studied included patients ranging from 22 years of age to 64 years of age. The youngest patient included in the study was a female patient aged 18

years, while the oldest member of the cohort was a male aged 64 years. The study cohort consisted of 60 patients. Amongst them, 45% (n=27) were males whereas majority of the cohort was formed by females (55%).

An objective parameter evaluated as a primary objective in the study was to assess if there is a difference between pre-operative & post-operative ONSD values. Data was evaluated using Wilcoxon's matched pairs signed rank test.

Comparison By Wilcoxon's Matched Pairs Signed Rank Test
Mean Std.Dv. N Diff. Std.Dv. Diff.
Pre_REm 4.82 0.907
Post_REm 4.13 0.427 60 0.69 0.677Pre_LEm 4.86 0.889
Post_LEm 4.13 0.432 60 0.72 0.633
Valid T Z p-level

Pre_REm & Post_REm 60 164.5 5.524883 < 0.001
Pre_LEm & Post_LEm 60 124 5.823028 < 0.001
Apart from this, another objective of the study was to assess the intra – observer variability. Intraclass correlation coefficient system was used.

Intraclass Correlation Coefficient
Single measures b Intraclass correlation a 95% Confidence Interval

Right eye – pre-operative
0.971 0.955 to 0.981

Left eye – pre-operative
0.975 0.962 to 0.985

Right eye – post-operative
0.933 0.899 to 0.957

Left eye – post-operative
0.941 0.902 to 0.965

a The degree of absolute agreement among measurements.
b Estimates the reliability of single ratings.

Right eye – preoperative :- A intra class correlation coefficient is > 0.7 , there is strong intra observer agreement for right eye.
0.00
1.00
2.00
3.00
4.00
5.00
6.00
7.00
0 20 40 60 80
Pre_RE1 Pre_RE2 Pre_RE3

Left eye – preoperative :- A intra class correlation coefficient is > 0.7 , there is strong intra observer agreement for left eye.

Right eye – postoperative :- A intra class correlation coefficient is > 0.7 , there is strong intra observer agreement for right eye.
0.00
1.00
2.00
3.00
4.00
5.00
6.00
7.00
0 20 40 60 80
Pre_LE1 Pre_LE2 Pre_LE3 0.00
1.00
2.00
3.00
4.005.00
6.00
0 20 40 60 80
Post_RE1 Post_RE2 Post_RE3

Left eye – postoperative ONSD :- A intra class correlation coefficient is > 0.7 , there is strong intra-observer agreement for left eye.

A secondary objective in the study was to assess the efficiency of system based on time taken. The mean time taken to perform per patient was 11.48 minutes pre-operatively and 11.67 minutes postoperatively.

DISCUSSION:
Despite a relatively long history of innovative thinking involving the pursuit of suitable techniques for non-invasively assessing ICP, the process is still in a relatively exploratory phase. The main limitations remain inadequate diagnostic accuracy for consistently detecting raised ICP, poor quantitative estimation of ICP and lack of continuous monitoring capability. Most methods appear suitable to identify subjects with low to normal ICP or very high ICP, but are poor at detecting moderately raised ICP, which arguably, is the most important group. The idea of combining selected non-invasive techniques to improve accuracy, in a 'non-invasive multi-modality model' is certainly appealing in principle.

Non-invasive ICP assessment is still most suitable as a screening tool for patients with suspected raised ICP. Patients in a neurocritical care unit often require continuous ICP monitoring, usually as part of a multimodal monitoring approach. These objectives are currently only achievable using invasive monitoring techniques.
0.00
1.00
2.00
3.00
4.00
5.00
6.00
0 20 40 60 80
Post_LE1 Post_LE2 Post_LE3

This study has identified measurement of the ONSD using transorbital ultrasound as a promising technique.

1. Mean ONSD:
Most of the available literature evaluating the use of ONSD measurement in adults are from studies performed in the ED or ICU, using transorbital ultrasound. As a result, the reference standard against which ONSD was measured in these studies was often clinical or radiological evidence of raised ICP. The most commonly used and set ONSD cutoff value was > 5mm [7] [8] [9] [10] [11] [12] [13]. Not surprisingly this value is different in studies comparing ONSD to invasive measurement of CSF pressure, with a range of 4.1 -5.9 mm.

In our observation the mean ONSD is found to be 4.8 mm and it correlates with the abovementioned range. We suggest a value above 4.5mm to be considered as a marker or cut off forraised ICP in screening of patients in ICU with suspicion of raised ICP. Moreover, as there is no difference in the cut off value for age and sex, we still propose to take 4.5 mm as the cut off value irrespective of age and sex.

Rajajee et al. performed a prospective blinded observational study on 65 patients in the ICU. All patients in the study had either had an EVD or intraparenchymal ICP monitor in situ. The authors used individual as well as mean ONSD values to account for possible fluctuation in the ICP during ONSD measurement. For the individual ONSD 77 measurements the median was 0.53 cm for ICP > 20 mmHg, and 0.4 cm for ICP < 20 mmHg ($p < 0.0001$). An ONSD of 0.48 cm demonstrated a sensitivity of 96% and specificity of 94% for predicting ICP > 20 mmHg. The authors suggested that the optimal criteria for ONSD measurement should be validated internally. The same author later published a retrospective review of this data, aiming to assess the accuracy of ONSD measurement in patients with acutely fluctuating ICP. 73 patients were included in the review. 'Acutely fluctuating ICP' was defined as measurements above and below 20 mmHg during the same ONSD measurement cluster or a change in ICP of > 10 mmHg, demonstrating that the specificity and positive predictive value of ONSD measurement declined when ICP fluctuated acutely, suggesting this may be due to a delay in reversal of the nerve sheath distension [14].

A blinded cross-sectional study conducted only in Chinese patients also used a lumbar CSF opening pressure of 20 cm H20. The study conducted by Wang et al included 279 subjects and sought to identify potential factors influencing the relationship between ONSD and ICP. A much lower ONSD cut-off point of 4.1 mm, with a sensitivity of 95% and a specificity of 92% was reported in this study. The authors

described several possibilities for the discrepancy between their findings and previous reports, acknowledging that little was known about the factors influencing the relationship between ICP and ONSD, ascribing the inconsistency of their lower ONSD values to differences in ethnicity and severity of illness [15].

2. Repeatability & intra-observer variability:

The concepts of repeatability and user variability remain core aspects of a suitable diagnostic modality. Specifically, for transorbital ultrasonography, the most appropriate plane of imaging and the requirement for bilateral image acquisition remain relevant questions, especially with the paucity of data on this technique.

Early work done by Ballantyne examined the observer variation in normal adult patients, demonstrating a median intra-observer variation of ± 0.2 – 0.4 mm and an inter-observer variation of ± 0.6 – 0.7 mm, reporting that standardization of the technique reduced observer variability [16].

The factors described by Bauerle et al were specifically addressed in the current study, bytesting the relationship between repeat measurements performed in the same plane of the same eye, as a test for repeatability, and by testing intra observer reliability [17]. Three ONSD measurements were performed to allow adequate testing for the repeatability of measurements.

The results from this study demonstrated excellent repeatability between each of the three ONSD measurements performed in the same plane of each eye i.e. > 0.9 intra class correlation coefficient, there is strong intra-observer agreement. The intra-observer variability was excellent with mean ONSD values of 4.82 (SD 0.91) and 4.86 mm (SD 0.89), in the pre-operative phase for right and left eye respectively. These findings confirm that ONSD measurement on ultrasound yields consistent and acceptable intra-observer variability.

3. Difference between pre- and post-operative values of ONSD:

Bhandari et al, assessed ONSD amongst 69 patients undergoing Ventriculoperitoneal shunt surgery; preoperatively as well as post-operatively. They reported a preoperative value of 5.80+/-0.63 mm and a Post-operative value of 4.52+/-0.72mm. This study was limited by its application to patients of ventriculo-peritoneal shunt surgery only.[18]
In our observational study also; we have found that there is significant difference between the values of ONSD in patients with preoperative and postoperative status. Mean values in Right eye pre operatively were 4.82 mm and in the Left eye were 4.86 mm. Post-operative measurements yielded a mean of 4.13 mm for both the eyes. This was found to be statistically significant. $p < 0.001$. This suggest that ONSD can be used as a bed side procedure for the serial monitoring of patients in the neurocritical care.

In 4 patients we have observed rather increase or no change in the ONSD. Out of 4 patients 2 patients were found to have intraventricular haemorrhage and two with post op significant venous infarction.

4. Efficacy of study:

One of the aims was to see the cost and time effectiveness of measuring ONSD via ultrasonography. Cost-effectiveness could not be studied as the facility is provided free of charge at the centre. It was however observed that the Mean time taken per patient was 11.48 minutes pre-operatively and 11.67 minutes post-operatively.

CONCLUSION:

This study illustrates the feasibility of non-invasive transorbital ultrasound for assessing optic nerve sheath diameter (ONSD) and to use it for the monitoring of patients in neurology intensive care units for the assessment of raised ICP as a noninvasive tool. Preliminary results demonstrate a significant difference between ONSD of patients before and after neurosurgical procedure. This supports the suggested hypothesis of a relationship between deformability of the ONS and ICP. ONSD measurement on ultrasound yields consistent and acceptable intra-observer variability and repeatability. It can be done on the bedside be repeated as many times as required within few minutes.

The difficulty in describing a universally acceptable reference range is largely due to variation in the definition of raised ICP, inter-observer variability, patient heterogeneity and a limited understanding of the elastic characteristics of the ONS. Despite clear description of a strong relationship, the optimism surrounding this technique is blurred by the lack of consensus regarding optimal cut-off values. Further validation of this technique in prospective, blinded studies would be helpful.

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